UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MINUTEMAN HEALTH, INC.,	)	
	)	
Plaintiff,	)	
	)	**Civ. Action No.**
v.	)	**16-11570-FDS**
	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER ON PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGEMENT

SAYLOR, J.

This is an action brought under the Administrative Procedure Act ("APA") challenging certain regulations promulgated by the Department of Health and Human Services ("HHS") under the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010).

Minuteman Health, Inc. is a nonprofit health-insurance provider that offered plans in Massachusetts in 2014, and in both Massachusetts and New Hampshire from 2015 to 2017. In 2014, it was required under HHS and Massachusetts regulations implementing the ACA's risk-adjustment program to pay 71% of its gross premium revenues to the program. In 2015, it was required to pay 40% of its New Hampshire revenues and 39% of its Massachusetts revenues. Perhaps unsurprisingly, it was not able to survive the loss of such a huge percentage of its revenues. It is now in receivership and is not offering plans to subscribers.

In substance, Minuteman challenges the HHS regulations that forced it to make those

large transfer payments. It contends that the regulations at issue (1) were arbitrary and capricious, and therefore in violation of the APA, 5 U.S.C. § 706, and (2) were beyond HHS's statutory authority because they contravene the statute providing for risk adjustment, 42 U.S.C. § 18063.

The issues posed in this lawsuit are far from simple. The ACA is a notoriously complex statute, health insurance is notoriously difficult to administer effectively, and the federal health-care bureaucracy is notoriously cumbersome. The implementation of the statute and its regulations can hardly be called an unqualified success, and it appears to have triggered a host of unintended consequences. But the role of this Court is not to sit in judgment on the wisdom of the law, nor is it to judge the actions of HHS with the benefit of hindsight. Rather, it is to consider this specific challenge to certain regulations implemented under the act by HHS, and to analyze that challenge according to a specific legal framework: in essence, to determine whether HHS acted arbitrarily or unreasonably based on the record before it at the relevant time.

The essential facts are not disputed, and both parties have cross-moved for summary judgment. In substance, the Court concludes that HHS acted within the bounds of its authority, even when the consequences of its choices may not always have been optimal. Accordingly, and for the reasons set forth below, defendant's motion will be granted and plaintiff's motion will be denied.

I. Background

A. Factual Background

1. The Patient Protection and Affordable Care Act

The ACA was passed to regulate health insurance in the United States. Among other things, it "bars insurers from taking a person's health into account when deciding whether to sell health insurance or how much to charge"; "requires each person to maintain insurance coverage

or make a payment to the Internal Revenue Service"; and "gives tax credits to certain people to make insurance more affordable." *King v. Burwell*, 135 S. Ct. 2480, 2485 (2015).

Congress recognized, however, that prohibiting insurers from denying coverage to individuals based on their health status, combined with insurers' lack of knowledge of the health status of the anticipated new enrollees, would create a substantial risk of premium volatility. To alleviate the effects of that uncertainty, the ACA established three premium-stabilization programs, colloquially known as the "3Rs": the reinsurance, risk-corridors, and risk-adjustment programs. *See generally* 42 U.S.C. §§ 18061-18063.[1] While reinsurance and risk corridors were temporary programs meant to stabilize premiums in the first few years of the ACA's implementation and have now been discontinued, the risk-adjustment program, which is the subject of this litigation, is permanent. *See* Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, 77 Fed. Reg. 17,220, 17,221 (Mar. 23, 2012) ("Premium Stabilization Rule"); *see* 42 U.S.C. §§ 18061(b)(1)(A), 18062(a), 18063.

The goal of the risk-adjustment program is to spread the costs of covering higher-risk members across insurers throughout a given state, thereby reducing incentives for insurers to engage in "risk-avoidance" techniques, such as designing or marketing their plans in ways that tend to attract healthier individuals, who cost less to insure. Mark A. Hall, *Risk Adjustment Under the Affordable Care Act: Issues and Options*¸ 20 KAN. J.L. & PUB. POL'Y 222, 224 (2011). In broad terms, it requires issuers with healthier members to pay into the program,

[1] HHS does not ordinarily employ the use of hyphens when it uses a phrasal adjective—that is, a phrase used as an adjective that precedes the noun it modifies. Thus, for example, according to HHS, the ACA has a "risk adjustment program" rather than a "risk-adjustment program." This has the effect of making difficult-to-read materials even more difficult, as the reader has to sort through each such set of words to ascertain which words are modifiers and what words they modify. *See generally* BRYAN A. GARNER, GARNER'S MODERN AMERICAN USAGE 625-28 (3d ed. 2009). For the sake of clarity, this opinion will generally use hyphens in phrasal adjectives, even when doing so alters a quotation. The Court hopes that this moderate increase in readability is worth the small price paid in technical accuracy.

which in turn provides subsidies to issuers with less-healthy members.

The key provisions of the statute are contained within a single, short section. It provides that "each State shall assess a *charge* on health plans and health insurance issuers . . . if the actuarial risk of the enrollees of such plans or coverage for a year is *less* than the average actuarial risk of all enrollees in all plans or coverage in such State for such year that are not self-insured group health plans," and, correspondingly, "each State shall provide a *payment* to health plans and health insurance issuers . . . if the actuarial risk of the enrollees of such plans or coverage for a year is *greater* than the average actuarial risk of all enrollees in all plans and coverage in such State for such year that are not self-insured group health plans." 42 U.S.C. § 18063(a) (emphases added).

Congress delegated to HHS the responsibility for administering many of the programs under the ACA, including the risk-adjustment program. *See id.* § 18063(b) ("The Secretary [of Health and Human Services], in consultation with States, shall establish criteria and methods to be used in carrying out the risk-adjustment activities under this section.").[2] Under the ACA, HHS was to promulgate overarching standards for the risk-adjustment program, and the states would operate the program independently within those guidelines. *See* 42 U.S.C. § 18041(c); 45 C.F.R. § 153.310. The statutory scheme allowed HHS to operate the program on behalf of any state that chose not to do so. 45 C.F.R. § 153.310(a)(2); *see* 42 U.S.C. §§ 18041(c)(1), 18063. In practice, the vast majority of states opted from the beginning to allow HHS to administer the program. The only state to run its own program was Massachusetts, and even Massachusetts

[2] The other defendants in this case—the Centers for Medicare and Medicaid Services ("CMS"); Sylvia Matthews Burwell, the Secretary of the Department of Health and Human Services; and Andrew Slavitt, the Acting Administrator for the Centers for Medicare and Medicaid Services—are all officials of or agencies within HHS. Defendants' brief states that HHS delegated certain responsibilities to CMS and the Center for Consumer Information and Insurance Oversight ("CCIIO"), but does not detail which responsibilities those were. In keeping with both parties' practice throughout the briefing, the Court will refer to defendants collectively as "HHS."

ceded responsibility to HHS beginning in the 2017 benefit year. *See* HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 15,410, 15,439 (Mar. 11, 2013) ("2014 Final Rule"); HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12,204, 12,230 (Mar. 8, 2016) ("2017 Final Rule").

Other parts of the ACA relevant to this action include the Consumer Operated and Oriented Plan Program (the "CO-OP" program), 42 U.S.C. § 18042, and the actuarial categorization of plans on the Health Benefit Exchanges, *id.* § 18022(d).

The CO-OP program, among other things, makes loans available to "qualified nonprofit health-insurance issuers" in order to encourage new entrants and bolster competition in the health-insurance market. *Id.* § 18042(b)(1); (Pl. Mem. in Supp. Summ. J. Ex. 11); *see also* 42 U.S.C. § 18042(c)(4) ("[A]ny profits made by the organization are required to be used to lower premiums, to improve benefits, or for other programs intended to improve the quality of health care delivered to its members."). CO-OP loan applicants must submit business plans to HHS, which, if approved, are incorporated into the final loan agreement. (Pl. Mem. in Supp. Summ. J. Exs. 11, 12). Congress appropriated $6 billion in the ACA to assist the launch of the CO-OP program. 42 U.S.C. § 18042(g).

The Health Benefit Exchanges are state-run insurance marketplaces created by the ACA to facilitate consumer choice and competition. 42 U.S.C. §§ 18031-18033. To allow consumers to compare products more easily, health plans sold on the exchanges are regulated in various ways. *Id.* §§ 18021-18024. Most relevant here, health plans sold on the exchanges are categorized as either catastrophic plans, which are only available to certain groups of enrollees, or one of four "metal levels": platinum, gold, silver, or bronze. *Id.* § 18022(d), (e). The metal levels correspond to the actuarial value of the plan—that is, the percentage of the full actuarial

value of the benefits provided under the plan that the plan will actually cover. A platinum plan has an actuarial value of 90%, gold 80%, silver 70%, and bronze 60%. *Id.* § 18022(d).

2. Risk-Adjustment Methodology

As described by HHS, the risk-adjustment program "is intended to provide payments to health-insurance issuers that attract higher-risk populations, such as those with chronic conditions, and eliminate incentives for issuers to avoid higher-risk enrollees." Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 65,046, 65,048 (Oct. 30, 2013). "The risk-adjustment program is intended to reduce or eliminate premium differences between plans based solely on expectations of favorable or unfavorable risk selection or choices by higher-risk enrollees in the individual and small-group market. [It] also serves to level the playing field inside and outside of the Exchange, reducing the potential for excessive premium growth or instability within the Exchange." Premium Stabilization Rule, 77 Fed. Reg. at 17,230. "Risk-adjustment transfers are intended to reduce the impact of risk selection on premiums while preserving premium differences related to other cost factors, such as the actuarial value, local patterns of utilization and care delivery, local differences in the cost of doing business, and, within limits established by the Affordable Care Act, the age of the enrollee." HHS Notice of Benefit and Payment Parameters for 2014, 77 Fed. Reg. 73,118, 73,139 (Dec. 7, 2012) ("2014 Proposed Rule"). "The risk-adjustment methodology proposed in the proposed rule, which HHS would use when operating risk adjustment on behalf of a State, is based on the premise that premiums should reflect the differences in plan benefits and plan efficiency, not the health status of the enrolled population." 2014 Final Rule, 78 Fed. Reg. at 15,417.

a. Procedure

HHS sets the risk-adjustment formula in advance of each benefit year through a notice-

and-comment rulemaking process. *See* 45 C.F.R. §§ 153.100(b)-(c), 153.320. Although HHS goes through separate rulemakings for each benefit year, since 2014, the inaugural year of the program, "the record for each Annual Benefit Rule incorporates the records for each of the preceding Annual Benefit Rules." (*See* Index to the Rulemaking Record at 3, n.2). HHS sets the parameters ahead of the applicable benefit year, with the intention that insurers will be able to rely on the methodology to price their plans appropriately. Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 76 Fed. Reg. 41,930, 41,932-33 (July 15, 2011) (proposed rule); *see also* HHS Notice of Benefit and Payment Parameters 2018, 81 Fed. Reg. 94,058, 94,702 (Dec. 22, 2016) ("2018 Final Rule") (explaining the importance of setting rules ahead of time and describing comments supporting that practice).

To initiate the rulemaking process, HHS publishes a proposed Notice of Benefit and Payment Parameters ("NBPP"), including a proposed risk-adjustment formula, in November or December of the year two years prior to the applicable benefit year—thus, for example, for the 2014 benefit year, HHS issued the proposed NBPP on December 7, 2012. 2014 Proposed Rule, 77 Fed. Reg. 73,118. The public then has an opportunity to comment on the proposed rule. The final rule is published in February or March of the year prior to the applicable benefit year—for example, the final rule for the 2014 benefit year was published on March 11, 2013. 2014 Final Rule, 78 Fed. Reg. 15,410.[3]

[3] The final 2014 rule was amended later in 2013. Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 65,046 (Oct. 30, 2013). That amendment modified the transfer formula in the risk-adjustment methodology for states that use "family tiering." 78 Fed. Reg. at 65,055-56. A further amendment in November 2013 corrected typographical errors from the 2014 Final Rule. HHS Notice of Benefit and Payment Parameters for 2014; Correcting Amendment, 78 Fed. Reg. 66,653 (Nov. 6, 2013).

The notice-and-comment period for the 2018 benefit year took place somewhat earlier—the rule was proposed in September 2016 and finalized in December 2016. HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 61,456 (Sept. 6, 2016) ("2018 Proposed Rule"); 2018 Final Rule, 81 Fed. Reg. 94,058 (Dec. 22, 2016).

It appears that HHS had ambitions to provide a proposed rule in October of the year two years prior to the

In addition to the final rule setting out the detailed parameters of the risk-adjustment formula, HHS published additional materials and sought public comment in other ways prior to the first year of the program. First, on September 12, 2011, the CMS Center for Consumer Information and Oversight published a white paper titled "Risk Adjustment Implementation Issues." The white paper explained that "[c]omments sent in response . . . will inform the HHS-developed Federally-certified risk-adjustment methodology, which will be released as part of a Federal Payment Notice that will appear in the Federal Register, and will include a draft notice and a comment period before the notice (and methodology) are finalized. Responses to the white paper may be submitted on an ongoing basis in advance of the draft notice, slated for Fall 2012." (Def. Mot. for Summ. J. Ex. B at 3-4). Second, following a notice of proposed rulemaking and a comment period, HHS published a rule titled "Standards Related to Reinsurance, Risk Corridors and Risk Adjustment" on March 23, 2012, which promulgated regulations now codified at 45 C.F.R. Part 153. The regulations included definitions, provisions concerning administration of the program as between HHS and the states, and an outline of the components of the risk-adjustment methodology to be included in the forthcoming NBPP. Premium Stabilization Rule, 77 Fed. Reg. 17,220; *see* 45 C.F.R. §§ 153.20, 153.320.[4] Third, on May 1, 2012, HHS published

applicable benefit year and the final rule in the following January. *See* Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 76 Fed. Reg. 41,930, 41,933 (July 15, 2011) (proposed rule).

[4] 45 C.F.R § 153.320(b) provides:

> The publication of a risk-adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters . . . must include:
>
> (1) A complete description of the risk-adjustment model, including—(i) Draft factors to be employed in the model, including but not limited to, demographic factors, diagnostic factors, and utilization factors, if any, the dataset(s) to be used to calculate the final coefficients, and the date by which final coefficients will be released in guidance; (ii) The qualifying criteria for establishing that an individual is eligible for a specific factor; (iii) Weights assigned to each factor; and (iv) The schedule for the calculation of individual risk scores.
>
> (2) A complete description of the calculation of plan average actuarial risk.

a bulletin outlining its intended approach to administering risk adjustment on behalf of a state that chooses not to run its own program. (A.R. 634-45).[5] Fourth, on May 7 and 8, 2012, HHS hosted a public meeting to discuss that approach. 2014 Final Rule, 78 Fed. Reg. at 15,414.

b. Initial 2014 Rule

The original methodology embodied in the 2014 Benefit Rule is generally as follows. First, the actuarial risk of each enrollee is measured. That figure is calculated through a "risk-adjustment model" that uses demographic and diagnostic data to determine the average predicted relative cost of insuring an enrollee. 2014 Final Rule, 78 Fed. Reg. at 15,419. Second, risk scores for each enrollee in a plan are aggregated to determine an overall "plan average risk score," or "plan liability risk score." *Id.* at 15,432. Third, a "transfer formula" compares each plan within a state insurance market to the average in order to determine risk-adjustment charges (billed to those insurers whose predicted costs are lower than the state average) and risk-adjustment payments (received by those insurers whose predicted costs are higher than the state average). 2014 Proposed Rule, 77 Fed. Reg. at 73,139; 2014 Final Rule, 78 Fed. Reg. at 15,431.

Since 2011, when the planning for the 2014 benefit year began, HHS has treated the risk-adjustment program as "self-funded" or "budget-neutral," meaning that money collected from low-risk plans is the only source of funding for the payments to high-risk plans. (Def. Mot. for Summ. J. Ex. B at 13-16). Its transfer formula is accordingly designed so that the charges to plans with healthier members will equal the payments to plans with less-healthy members.

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(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk-adjustment data-collection approach.

(5) The schedule for the risk-adjustment program.

[5] Citations to "A.R. __" refer to the administrative record in this case, which was manually filed with the Court. Wherever possible, the Court has endeavored to cite published documents and electronically filed exhibits instead of the administrative record, as the former are comparatively accessible.

According to HHS, "[t]he risk-adjustment methodology addresses three considerations: (1) the newly insured population; (2) plan metal levels and permissible rating variation; and (3) the need for inter-plan transfers that net to zero. . . . Transfers depend not only on a plan's average risk score, but also on its plan-specific cost factors relative to the average of these factors within a risk pool within a state." 2014 Final Rule, 78 Fed. Reg. at 15,417. The rule "[a]djusts payment transfers for plan metal level, geographic rating area, induced demand, and age rating, so that transfers reflect health risk and not other cost differences." *Id.*

More specifically, the risk-adjustment model calculates the relative actuarial risk of each enrollee as follows.[6] The model starts with demographic data, and assigns a numerical coefficient based on an individual's age and sex. 2014 Final Rule, 78 Fed. Reg. at 15,422-23 & tbl.2. Then, diagnostic data are incorporated using a hierarchical condition category ("HCC") classification system, based on, but different from, Medicare's HCC system. 2014 Proposed Rule, 77 Fed. Reg. at 73,128-29. HHS assigns numerical coefficients for each HCC, which "represent the predicted relative incremental expenditures" for that HCC. *Id.* at 73,130. If an individual has multiple unrelated diagnoses, those coefficients are summed (HCCs do not accumulate for related diagnoses; rather, the individual is assigned the highest HCC in a given category for which he or she meets the criteria). *Id.* at 73,128; 2014 Final Rule, 78 Fed. Reg. at 15,422.

[6] There are actually fifteen risk-adjustment models, one for each combination of metal level (platinum, gold, silver, bronze, and catastrophic) and age group (adult, child, and infant). 2014 Final Rule, 78 Fed. Reg. at 15,417. That is because of "inherent clinical and cost differences in the adult (age 21+), child (age 2-20), and infant (age 0-1) populations," with especially pronounced differences for infants, and because the risk associated with insuring an individual in a gold plan is greater than the risk associated with insuring the same individual in a catastrophic plan, because the total value of the catastrophic plan is less. *Id.* at 15,419; 2014 Proposed Rule, 77 Fed. Reg. 73,129-30. In addition, catastrophic plans are risk-adjusted in a separate pool from the metal-level plans because of the unique characteristics of the risk pool—consisting only of individuals under the age of 30 or individuals for whom insurance is deemed to be unaffordable. 2014 Final Rule, 78 Fed. Reg. at 15,418-19, 15,431.

The model uses diagnostic data from the same benefit year for which it is calculating risk-adjustment transfers in assigning HCCs to enrollees, in what is known as a "concurrent" model. 2014 Proposed Rule, 77 Fed. Reg. at 73,127-28; 2014 Final Rule, 78 Fed. Reg. at 15,417, 15,419-20. This is in contrast to a "prospective" model, where the individual's documented diagnoses for past years are used to estimate his or her risk for the upcoming benefit year. 2014 Proposed Rule, 77 Fed. Reg. at 73,127-28. According to HHS, while the prospective model more closely approximates how insurers set their rates, a concurrent model is "better able to handle changes in enrollment than a prospective model because individuals newly enrolling in health plans may not have prior data available that can be used in risk adjustment." *Id.*; (*see* Def. Mot. for Summ. J. Ex. B at 6-7).

To calculate the demographic and HCC numerical coefficients, HHS started with a database containing enrollee-specific clinical utilization and expenditures relating to more than 500 million claims from approximately 100 commercial health-insurance payers covering individuals living in all states, aged 0-64. 2014 Proposed Rule, 77 Fed. Reg. at 73,127. It used that data to calculate expenditures for each enrollee and adjusted the figure for metal level to arrive at a predicted plan liability for an enrollee with a given age, sex, HCC, and coverage level. *Id.* That data was then fed into a statistical regression to calculate the coefficients, which "represent the predicted relative incremental expenditures for each category or HCC." *Id.* at 73,130.

The sum of the demographic coefficient and the diagnostic coefficient(s) was then multiplied by a cost-sharing reduction ("CSR") adjustment factor. The CSR adjustment factor is designed to account for "increased plan liability due to increased utilization of health care services" by certain low-income and/or Native American enrollees who are eligible for premium

subsidies. 2014 Final Rule, 78 Fed. Reg. at 15,421-22 & tbl.1; *see* 2014 Proposed Rule, 77 Fed. Reg. at 73,138; *see also* 42 U.S.C. § 18071. The resulting figure is an enrollee's "individual risk score." (Hearing Tr. 60:7-22); *see* 2014 Proposed Rule, 77 Fed. Reg. at 73,139.

The plan average risk score is essentially a member month-weighted average of the individual risk scores of the enrollees of a given plan, slightly modified to account for the rule that only three children can count toward the build-up of family rates.[7] It is calculated by summing the products of each enrollee's risk score and the number of months that enrollee was enrolled in the plan, and dividing that sum by the sum of the number of months each billable member was enrolled in the plan, where billable members exclude children who do not count towards family rates. 2014 Final Rule, 78 Fed. Reg. at 15,432.

"Conceptually, the goal of payment transfers is to provide plans with payments to help cover their actual risk exposure beyond the premiums the plans would charge reflecting allowable rating and their applicable cost factors. In other words, payments would help cover excess actuarial risk due to risk selection." 2014 Final Rule, 78 Fed. Reg. at 15,430. Accordingly, HHS set a given plan's transfer amount to equal the difference between two estimated premiums, which can be thought of as ideal premiums that a plan would charge to perfectly cover its expenditures and margins: (1) the estimated premium for that plan with enrollees it has, who may represent greater- or less-than-average actuarial risk (the premium with risk selection), and (2) the estimated premium for that plan with enrollees of average risk (the premium without risk selection), such that the transfer is positive when the plan has greater-than-average risk and negative when the plan has less-than-average risk. 2014 Final Rule, 78 Fed.

[7] "If risk scores were calculated as the member month-weighted average of all enrollee risk scores, plan average risk scores would tend to misrepresent the risk issuers take on for family policies that include children that do not count toward family rates." 2014 Proposed Rule, 77 Fed. Reg. at 73,141.

Reg. at 15,430.

In order to get from a plan's risk score—a number representing the cost of providing care to the plan's risk-selected enrollees *relative* to the cost of providing that same level of care to enrollees with average risk—to a dollar figure representing the estimated premium, HHS chose to use the statewide average premium as a conversion factor. 2014 Proposed Rule, 77 Fed. Reg. at 73,139; 2014 Final Rule, 78 Fed. Reg. at 15,432. The average premium of a given plan is "based on the total premiums assessed to enrollees, including the portion of premiums that are attributable to administrative costs." 2014 Proposed Rule, 77 Fed. Reg. at 73,142. The statewide average premium is "calculated as the enrollment-weighted mean of all plan average premiums of risk-adjustment covered plans in the applicable risk pool in the applicable market in the State." *Id.*; *see* 2014 Final Rule, 78 Fed. Reg. at 15,431-32. Thus, both of the estimated premiums in the transfer formula are based on the statewide average premium, which is one of several multipliers making up each term.

HHS, however, also wanted to ensure that transfers would not "reflect liability differences attributed to cost factors other than risk selection." 2014 Final Rule, 78 Fed. Reg. at 15,431; *see* 2014 Proposed Rule, 77 Fed. Reg. at 73,139 ("Risk-adjustment transfers are intended to reduce the impact of risk selection on premiums while preserving premium differences related to other cost factors, such as the actuarial value, local patterns of utilization and care delivery, local differences in the cost of doing business, and, within limits established by the Affordable Care Act, the age of the enrollee."). Therefore, in calculating the estimated premiums, it included a series of "premium-adjustment terms," detailed below, which (like the numbers assigned in the risk-adjustment model) are "relative measures that compare how plans differ from the market average with respect to the cost factors." 2014 Final Rule, 78 Fed. Reg. at

15,430-31.

To calculate the estimated premium for a given plan with risk selection, the formula multiplies the plan's liability risk score by two premium-adjustment terms: an "induced-demand" factor and a "geographic-cost" factor. *Id.* at 15,431. The induced-demand factor is meant to "reflect[] differences in enrollee spending patterns attributable to differences in the generosity of plan benefits (as opposed to risk selection)"—in other words, a person with a more generous plan might consume more health care than the same person in a less generous plan. 2014 Proposed Rule, 77 Fed. Reg. at 73,143. The geographic-cost factor accounts for differences in plan costs across geographic areas to prevent transfers from "subsidiz[ing] high-risk plans in high-cost areas at the expense of low-risk plans in low-cost areas." *Id.* at 73,144. The resulting product is then normalized for the plan's share of overall state enrollment (such that the "'normalized' term would average to 1.0," *id.* at 73,141) and multiplied by the statewide average premium to arrive at a dollar figure, *id.*; 2014 Final Rule, 78 Fed. Reg. at 15,431.

To calculate the estimated premium for that plan, assuming it had enrollees of average risk, the transfer formula multiplies the same induced-demand and geographic-cost factors described above by two more premium-adjustment factors: a plan's "allowable-rating factor" and the actuarial value of the plan's metal level. The allowable-rating factor accounts for the fact that issuers are allowed to charge enrollees different premiums based on their age (within limits). 2014 Proposed Rule, 77 Fed. Reg. at 73,142-43; 2014 Final Rule, 78 Fed. Reg. at 15,433. The actuarial value of the plan "account[s] for relative differences between a plan's [actuarial value] and the market average [actuarial value]." 2014 Proposed Rule, 77 Fed. Reg. at 73,140.[8] "The [actuarial-value] adjustment helps to achieve the goal of compensating plans for

[8] The first half of the transfer formula, the estimated premium reflecting risk selection, "does not include an [actuarial-value] adjustment because the risk score reflects the plan's [actuarial value]." 2014 Proposed Rule, 77

risk selection while allowing other determinants of premiums—including the generosity of plan benefits—to be reflected in premiums." *Id.* at 73,142. As for the estimated premium with risk selection, the resulting product is normalized for the plan's share of statewide enrollment and then multiplied by the statewide average premium. 2014 Proposed Rule, 77 Fed. Reg. at 73,141; 2014 Final Rule, 78 Fed. Reg. at 15,431.

The output of the payment-transfer formula is a "per member per month . . . transfer amount for a plan within a rating area." 2014 Final Rule, 78 Fed. Reg. at 15,431. That amount is then multiplied by the plan's "billable member months," defined as the number of months during the risk-adjustment period that each billable member (excluding children who do not count towards family rates) is enrolled in the plan, to arrive at the plan's total risk adjustment for a given rating area. *Id.* at 15,431-32.

c. Changes to the 2014 Rule

Since 2014, HHS has maintained a position supporting model stability, and has elected not to rework the program's overarching methodology. *See* 2014 Final Rule, 78 Fed. Reg. at 15,418 ("Though we anticipate making future adjustments to the model, we seek to balance stakeholders' desire for a stable model in the initial years with introducing model improvements as additional data becomes available."); HHS Notice of Benefit and Payment Parameters for 2015, 79 Fed. Reg. 13,744, 13,753 (Mar. 11, 2014) ("2015 Final Rule") ("We believe it is important to maintain model stability in implementing the risk-adjustment methodology in the initial years of risk adjustment, and therefore do not intend to recalibrate the model in the initial

Fed. Reg. at 73,141; *see* 2014 Final Rule, 78 Fed. Reg. at 15,422-30 & tbls.2-7 (assigning different values to the demographic and diagnostic factors for plans of different metal level). "Additionally, the premium estimate reflecting risk selection does not include the allowable-rating factor adjustment. Thus, the difference between the premium estimates . . . provides an estimate of plan liability attributed to risk selection that is not compensated for through allowable-premium rating—our measure of actuarial risk." 2014 Proposed Rule, 77 Fed. Reg. at 73,141.

years."); HHS Notice of Benefit and Payment Parameters for 2016, 79 Fed. Reg. 70,674, 70,684 (Nov. 26, 2014) ("2016 Proposed Rule") ("We propose to continue to use the same risk-adjustment methodology finalized in the 2014 Payment Notice, with changes to reflect more current data . . . ."). However, there have been smaller, incremental adjustments over time.

Health plans are required to submit their risk-adjustment data to HHS by April 30 of the year following the benefit year. 45 C.F.R. § 153.730. HHS announces the transfer amounts by June 30. *Id.* § 153.310. Because of that schedule, and because HHS publishes its final rule in the early spring of the year prior to the applicable benefit year, by the time the 2014 results were available on June 30, 2015, the benefit rules for 2015 and 2016 had already been set to be largely the same as the 2014 Final Rule. *See* 2015 Final Rule, 79 Fed. Reg. 13,744 (Mar. 11, 2014); HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,750 (Feb. 27, 2015) ("2016 Final Rule").[9]

After the 2014 results were calculated, HHS proposed to update the model to include preventative-care costs in the 2017 rule and sought comment on how the risk-adjustment methodology could more accurately account for partial-year enrollees. HHS Notice of Benefit and Payment Parameters for 2017, 80 Fed. Reg. 75,488, 75,499-500 (Dec. 2, 2015) ("2017 Proposed Rule"). The final rule, published March 6, 2016, incorporated an adjustment for preventative-care costs and indicated that HHS would further explore adjustments for partial-year enrollees. 2017 Final Rule, 81 Fed. Reg. at 12,218-20. Later that month, HHS published a

[9] Although the methodology of the 2015 and 2016 rules was largely the same as the 2014 rule, HHS did makes some minor adjustments. The 2015 rule contained "updates to the risk-adjustment methodology . . . to account for certain private-market Medicaid expansion alternative plans" and "establishe[d] counting methods for determining small-group size for participation in the risk-adjustment and risk-corridors programs." 2015 Final Rule, 79 Fed. Reg. at 13,745. It also provided for a robust data-validation process. *Id.* at 13,752-71. For 2016, HHS "recalibrate[d] the HHS risk-adjustment models for the 2016 benefit year by using 2011, 2012, and 2013 claims data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan) to develop updated risk factors." 2016 Final Rule, 80 Fed. Reg. at 10,752; *see id.* at 10,759-72.

lengthy discussion paper and held a public meeting to discuss possible modifications to the risk-adjustment methodology, including adjustments for partial-year enrollment. (Def. Mot. for Summ. J. Ex. C (dated Mar. 31, 2016)); *see* 2017 Final Rule, 81 Fed. Reg. at 12,216, 12,220. Following the conference, HHS announced in a June 2016 press release that it would incorporate an adjustment for partial-year enrollment for the 2017 benefit year, and it finalized that adjustment in December 2016, as part of the 2018 Final Rule. 2018 Final Rule, 81 Fed. Reg. at 94,071-74. The 2018 Final Rule also stated that HHS

> did not propose to, and [is] not changing, the risk-adjustment methodology for the 2014, 2015, and 2016 benefit years. As these benefit years have already begun, we could not implement such a change prior to the applicable benefit year or provide advance notice to permit issuers to incorporate the applicable benefit year's risk-adjustment methodology in their rate setting. However, for the 2017 benefit year, we provided advance notice to issuers prior to rate setting, and believe an adjustment for partial-year enrollees will better compensate issuers with higher than average partial-year enrollees.

Id. at 94,073.

The 2018 Final Rule made additional changes to take effect beginning in the 2018 benefit year. HHS began to use pharmaceutical data to assign a limited number of HCCs. *Id.* at 94,074-76. It also "reduce[d] the Statewide average premium in the risk-adjustment transfer formula by 14 percent to account for the proportion of administrative costs that do not vary with claims." *Id.* at 94,099-100.

3. Minuteman Health

Plaintiff Minuteman Health, Inc. was created under the CO-OP program. (Pl. Mem. in Supp. Summ. J. Ex. 10 ¶¶ 28-29). HHS approved Minuteman's business plan and signed a loan agreement funding its initial formation in Massachusetts in August 2012. It signed an amendment in November 2013 allowing it to expand into New Hampshire. (*Id.* Ex. 10 ¶ 28).

Minuteman offered health plans in Massachusetts starting in 2014, the first year the ACA

came into effect, and entered the New Hampshire market in 2015. (*Id.* Ex. 10 ¶ 31). Its goal was to provide affordable health insurance in the individual and small-group markets by contracting with high-quality, low-cost health-care providers and excluding high-priced hospital systems from its network. (*Id.* Ex. 10 ¶¶ 12, 24-26). Minuteman priced its premiums significantly lower than many other issuers in the Massachusetts and New Hampshire markets. (*Id.* Ex. 10 ¶¶ 32-34).

In all the benefit years at issue here for which results are available, Minuteman's enrollees have collectively been healthier than average, and Minuteman has accordingly been required to pay into the risk-adjustment program. For the 2014 benefit year, Minuteman was required to pay 71% of its gross premium revenue into the risk-adjustment program. (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 2 at 11). For the 2015 benefit year, Minuteman was required to pay 40% of its gross New Hampshire premium revenue to the risk-adjustment program, and 39% ($6,110,676) of its gross Massachusetts premium revenue. (Pl. Mem. in Supp. Summ. J. Ex. 13 at 5).

The payment of such huge amounts—up to 71% of its gross revenue—has had a deleterious effect on Minuteman's business. Minuteman is now in receivership and will not be offering plans for the 2018 benefit year. (Hearing Tr. 3:21-4:4; Pl. Opp'n to Mot. to Strike Ex. A).

B. Procedural Background

Minuteman filed the complaint in this action on July 29, 2016. The amended complaint asserts one count for "Violations of Section 1343 of the ACA and the APA, 5 U.S.C. § 706." (Am. Compl. ¶¶ 208-15). It alleges that "[t]he Risk-Adjustment methodology developed and implemented by CMS, at the direction of HHS, is arbitrary, capricious, and unlawful" and that "HHS and CMS have gone beyond the bounds of their statutory directive, injecting unauthorized

factors into the Risk-Adjustment methodology, and failing to create a methodology that effects the directive of Congress." (*Id.* ¶ 215).

The parties have cross-moved for summary judgment. At the summary-judgment hearing, Minuteman dropped its challenge to the 2018 benefit rule. (Hearing Tr. 3:23-4:4). The government then filed a motion to strike all materials related to the 2018 benefit year (and certain other materials never presented to the agency in any benefit year) as materials that are outside the record.

II. Standard of Review

Summary judgment is ordinarily appropriate when the pleadings and evidence show that "there is no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, in cases involving review of agency action under the APA, the traditional Rule 56 standard does not apply due to the limited role of a court in reviewing the administrative record. *See Int'l Junior Coll. of Bus. & Tech., Inc. v. Duncan*, 802 F.3d 99, 106 (1st Cir.2015) ("The summary judgment 'rubric' also 'has a special twist in the administrative law context.'" (quoting *Associated Fisheries of Me., Inc. v. Daley*, 127 F.3d 104, 109 (1st Cir. 1997))). Rather, when administrative action is challenged under the APA "[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Coe v. McHugh*, 968 F. Supp. 2d 237, 240 (D.D.C. 2013); *S. Shore Hosp., Inc. v. Thompson*, 308 F.3d 91, 97-98 (1st Cir. 2002) ("That the parties brought the issues forward on cross-motions for summary judgment is not significant; substance must prevail over form, and the fact remains that the parties have presented this matter as a case stated[] on a fully developed administrative record.").

The Administrative Procedure Act provides that a reviewing court should "hold unlawful

and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706.

In *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Supreme Court established a two-step analysis for reviewing an agency's construction of a statute that it administers. *Id.* at 842–43. The analysis begins with "whether Congress has directly spoken to the precise question at issue." If Congress's intent is clear, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. If Congress has explicitly left a gap for the agency to fill, the agency's interpretation is "given controlling weight unless [it is] arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843–44; *see also Household Credit Servs., Inc. v. Pfennig*, 541 U.S. 232, 239 (2004).

Under the second step, the agency's construction is accorded substantial deference. *Chevron*, 467 U.S. at 844; *see also United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001). "This broad deference is all the more warranted when . . . the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (quoting *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991)). The court should not simply substitute its judgment for that of the agency. *See Mead*, 533 U.S. at 229 ("[A] reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular

statutory ambiguity simply because the agency's chosen resolution seems unwise.").

In determining whether agency action is arbitrary and capricious under the APA, the court must examine the evidence relied on by the agency and the reasons given for its decision. The agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *see Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 351-52 (1st Cir. 2004). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43.

Under the APA, an agency is required to respond to "relevant" and "significant" comments raised in the rulemaking process. *Public Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993). But this requirement is not "particularly demanding." *Id.* "[I]t is settled that 'the agency [is not required] to discuss every item of fact or opinion included in the submissions made to it in informal rulemaking.'" *Id.* (second alteration in original) (quoting *Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968)). "Instead, the agency's response to public comments need only 'enable [the reviewing court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Id.* (citing *Auto. Parts*, 407 F.2d at 335); *see also Del. Dep't of Nat. Res. & Envtl. Control v. Envtl. Prot. Agency*, 785 F.3d 1, 15 (D.C. Cir. 2015). "[C]omments which themselves are purely speculative

and do not disclose the factual or policy basis on which they rest require no response." *Home Box Office, Inc. v. Fed. Commc'ns Comm'n*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977).

A court reviewing agency action must judge that action by the reasons given by the agency; it is not permitted to supply its own reasoned basis not present in the administrative record. *Bowman Transp. Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974) ("[W]e may not supply a reasoned basis for the agency's action that the agency itself has not given . . . ." (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947))); *Sec. & Exch. Comm'n v. Chenery*, 318 U.S. 80, 87-88 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."). Additionally, the agency's action may only be judged against the information available to the agency at the time—namely, the materials in the administrative record. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). The reviewing court may, however "uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned." *Bowman Transp.*, 419 U.S. at 286; *see Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016).

III. Analysis

A. Motion to Strike

HHS has moved to strike all materials relating to the 2018 benefit year on the ground that it is "black-letter administrative law" that an agency action can only be judged on the materials before it at the time it made its decision. *See Hill Dermaceuticals, Inc. v. Food & Drug Admin.*, 709 F.3d 44, 47 (D.C. Cir. 2013); *Massachusetts v. Hayes*, 691 F.2d 57, 60 (1st Cir. 1982) ("'Simple fairness to those who are engaged in the tasks of administration, and to litigants, requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice.'" (quoting *United States v. L.A. Tucker Truck Lines*, 344 U.S. 33,

37 (1952))); *Bradley v. Weinberger*, 483 F.2d 410, 414-15 (1st Cir. 1973) (citing *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)).

Plaintiff's principal response is simply to contend that "except for discrimination against bronze plans, all of Minuteman's challenges to the 2014-2017 rules were raised either by Minuteman, by other commenters, or by the agency itself during the relevant rulemaking proceedings for those years, and are thus preserved for judicial review." (Pl. Opp'n to Mot. to Strike at 3). But even if true, that does not mean that this Court may judge the actions of the agency in 2014-2017 based on the content of the comments made in 2018; it can only do so based on what was before the agency at the relevant time. Therefore, while the existence of prior comments raising similar issues may provide the Court with a basis to determine whether the particular agency decisions contested by plaintiff in this action are arbitrary and capricious, it is not a reason to consider the 2018 materials.

Plaintiff further argues that in its 2018 comment, it petitioned for "reconsideration" of the 2014-2017 rules pursuant to 5 U.S.C. § 553(e); that HHS denied its petition; that when it denied the petition, the record before the agency included the 2018 materials; and that therefore the administrative record on review should include those materials. *See Am. Horse Prot. Ass'n, Inc. v. Lyng*, 812 F.2d 1, 5 (D.C. Cir. 1987).

The complaint, however, makes no allegation of an improper denial of any petition under § 553(e). Indeed, the first time plaintiff made any mention of that theory of recovery was in its summary judgment reply memorandum. (Pl. Reply in Supp. Summ. J. at 5-6). Therefore, that argument is untimely, and the Court need not consider it. *See Torres-Rios v. LPS Labs., Inc.*, 152 F.3d 11, 15-16 (1st Cir. 1998).

In any event, even considered on its merits, that theory is untenable. Although plaintiff

calls its comment a petition for "reconsideration," there is no such thing. In substance, plaintiff was seeking a modification of a rule with retroactive effect. (*See* Pl. Opp'n to Mot. to Strike at 3). The APA provides that "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). The APA defines "rule" as "the whole or a part of an agency statement of general or particular applicability *and future effect* designed to implement, interpret, or prescribe law or policy . . . ." *Id.* § 551(4) (emphasis added). That statute, by its terms, does not provide an interested party with the right to seek amendment to past rules with retroactive effect. Indeed, agencies are generally prohibited from promulgating retroactive rules, absent express permission from Congress. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

Plaintiff cites to no authority suggesting that interested parties have a right to petition agencies for retroactive rule changes, and the cases it cites are not on point. In particular, *Beverley Hospital v. Bowen*, 872 F.2d 483 (D.C. Cir. 1989), stands for the proposition that when a plaintiff has successfully challenged a regulation and it is ruled to be "void *ab initio*," the general prohibition on retroactive rulemaking does not prevent the agency from making "corrective adjustments" to afford plaintiff relief reflecting what the court has found to be illegal. *Id.* at 485-86. *Beverley Hospital* does not suggest that the agency has the power to make retroactive changes whenever an interested party so requests.[10]

Plaintiff further argues that its 2018 comment, which was submitted on October 6, 2016, was not requesting retroactive changes as to the 2016 and 2017 rules, because the 2016 and 2017

[10] Indeed, plaintiff itself acknowledged this in its opening memorandum, arguing that "[w]hile the Supreme Court has explained that an *agency's* power to promulgate a retroactive rule is limited," that does not prevent plaintiff from receiving retroactive relief if a Court invalidates a rule. (Pl. Mem. in Supp. Summ. J. at 32 n.12; *see also id.* at 42).

risk-adjustment transfers had yet to be calculated. (*See* Pl. Mem. in Supp. Summ. J. Ex. 13). But the HHS regulations require setting the payment-transfer formula in advance, so that issuers can set their premiums with the transfer methodology in mind. The fact that the 2016 transfer amounts would not be calculated until June 2017 is of no moment—as of October 2016, issuers could hardly change their 2016 premiums, and therefore changing the transfer formula at that time would implicate the same policy concerns as the prohibition on retroactive rulemaking. *See* 2018 Final Rule, 81 Fed. Reg. at 94,073 (explaining the importance of finalizing rules in time to allow issuers to incorporate the methodology in their rate setting).

Plaintiff has a somewhat stronger position with respect to the 2017 Final Rule, which was published on March 8, 2016 (prior to plaintiff's comment, which was submitted on October 6), but modified on December 22, 2016, to include adjustments for partial-year enrollment. *See* 2017 Final Rule, 81 Fed. Reg. 12,204; 2018 Final Rule, 81 Fed. Reg. 94,058. That timing superficially suggests that at the time plaintiff submitted its comment for 2018, it was not too late for HHS to consider its comments in making changes to the 2017 rule. But the particular modification lately made to the 2017 rule had been subject to notice and comment by way of a March 2016 discussion paper and public meeting and had been previously announced in a June 2016 press release. (Def. Mot. for Summ. J. Ex. C); *see* 2017 Final Rule, 81 Fed. Reg. at 12,216, 12,220. No other changes to the 2017 rule were noticed in those proceedings. The 2018 notice of proposed rulemaking did not generally request comment relating to the 2017 rule, and plaintiff's comments seeking changes going back to 2014 were certainly outside the scope of that proposal. Without notice of its intent to change the 2017 rule, HHS could not have otherwise altered it in response to comments on the 2018 rule. *See Am. Fed'n of Labor & Congress of Indus. Orgs. v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985) (explaining that the final rule must

be a "logical outgrowth" of the proposed rule and that "if the final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal" (quoting *Small Refiner Lead Phase-Down Task Force v. Envtl. Prot. Agency*, 705 F.2d 506, 547 (D.C. Cir. 1983))); 2018 Final Rule, 81 Fed. Reg. at 94,072-73 (summarizing concerns from commenters about making changes after the time for rate setting). Therefore, the notice of the proposed modification for partial-year enrollment did not effectively open the 2017 rule to the incorporation of any comment submitted for the 2018 rule.

To the extent that plaintiff contends that its October 2016 comment (which, again, was submitted as part of the 2018 benefit year notice-and-comment process and requested changes to the 2014-2017 benefit years) could have been considered a petition to amend the 2017 Final Rule, the Court cannot fault the agency for failing to treat it that way. It is true that HHS has not adopted any particular regulations concerning the form that petitions under § 553(e) must take. Nonetheless, merely requesting changes to past rules in a comment on a different proposed rule—without at least identifying the comment as a petition for amendment—is not sufficient to put the agency on notice that it must give its reasons for refusing to take the requested action. *See* 5 U.S.C. § 555(e); *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 948-49 (D.C. Cir. 2004), *abrogation on other grounds recognized by Perry Capital LLC v. Mnuchin*, 864 F.3d 591, 620-21 (D.C. Cir. 2017) (explaining that where letter did not request specific relief, was followed by a proper petition, was submitted in response to a solicitation for comments confined to another topic, and was outside the scope of the proceeding in which it was submitted, it was not a petition subject to judicial review). Indeed, the relief requested by plaintiff in its 2018 comment—that is, immediate changes to prior years' rules—is not relief that

would have resulted from a successful petition for rulemaking.[11] A successful petition would at most begin a new rulemaking process, wherein HHS would propose changes to prior years' rules and receive comments before making the changes plaintiff requested. *See Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 203 (2d Cir. 2004); *Am. Horse Prot. Ass'n*, 812 F.2d at 7-8.

Accordingly, the Court will generally decline to consider the 2018 materials in deciding whether HHS's rules for the 2014-2017 benefit years were arbitrary and capricious. However, because the 2018 Final Rule modified a portion of the 2017 Final Rule to include accounting for partial-year enrollees, the comments related to that adjustment appear to be properly part of the record. Furthermore, to the extent that plaintiff's 2018 comment and the documents submitted with it contain relevant background information about plaintiff, the Court will consider those materials.

Defendants also contend that that certain additional materials—mostly newspaper articles, but also testimony from various state insurance commissioners before the U.S. Senate Committee on Homeland Security and Governmental Affairs; a court transcript from a District of Columbia District Court decision; and the Commonwealth Health Insurance Connector Authority ("Health Connector") decision denying plaintiff's request for review of its 2014 risk-adjustment payment—should be struck because they were not before HHS in any benefit year. (Def. Mem. in Supp. Mot. to Strike Ex. A). Plaintiff admits that "these materials are not necessary for [its]

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[11] Plaintiff's 2018 comment complains that the proposed changes "would not go into effect until *benefit year 2018*" and calls that "unacceptable." (Pl. Mem. in Supp. Summ. J. Ex. 13 at 8). It goes on to say:

> HHS and CMS need to act ***now*** to mitigate the harm they have already caused and to prevent future harm and further destabilization of the health-insurance market. It is incumbent upon them to effectuate the purpose of the ACA—to expand access to high-quality health care regardless of health status and provide greater consumer choice. To do this, they must thoroughly and immediately fix the Risk-Adjustment methodology, apply those changes in the 2016 and 2017 benefit years as well as 2018 and apply them retroactively to 2014 and 2015.

(*Id.* (footnote omitted)).

arguments that the risk-adjustment rules violated the APA." (Pl. Opp'n to Mot to Strike at 15). Its only justification for including these materials is that the Court may take judicial notice of them.

Judicial notice is an evidentiary doctrine that may be used to admit "a fact that is not subject to reasonable dispute." *See* Fed. R. Evid. 201. Even if the Court were inclined to take judicial notice of materials such as newspaper articles—which, here, appear to be submitted in order to establish the very-much-disputed fact that HHS's risk-adjustment program is responsible for the current instability in the insurance market—those materials would still be outside the record that the Court may permissibly consider. In other words, question is not whether this Court can take judicial notice of them, but whether the agency should have taken notice of them at the time of its rulemaking. The Health Connector decision is relevant to the standing analysis, as noted below, but will not be considered in relation to whether HHS's rules were arbitrary and capricious. (Pl. Mem. in Supp. Summ. J. Ex. 19). The other materials do not appear to have been submitted to the agency in any rulemaking procedure, are irrelevant, and will therefore be struck.

Defendant's motion to strike will therefore be granted in part and denied in part.

B. Motions for Summary Judgment

1. Standing

Standing is a threshold question in every case. "If a party lacks standing to bring a matter before the court, the court lacks jurisdiction to decide the merits of the underlying case." *United States v. AVX Corp.*, 962 F.2d 108, 113 (1st Cir.1992). To satisfy the case-or-controversy requirement of Article III of the U.S. Constitution, a plaintiff bears the burden of establishing that it (1) has suffered an "injury-in-fact," (2) that the injury is "'fairly traceable' to the actions of the defendant[s]," and (3) "that the injury will likely be redressed by a favorable decision."

Bennett v. Spear, 520 U.S. 154, 162 (1997) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). These elements must be proved "with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561. The redressability element of standing requires that the requested relief directly redress the injury alleged. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 105-09 (1998). Plaintiff must establish that it is "likely," as opposed to merely "speculative," that its claimed injuries will be redressed by a favorable decision. *Lujan*, 504 U.S. at 561.

Counsel for plaintiff clarified at the hearing that its only claim as to the 2014 benefit year—when it was operating only in Massachusetts and Massachusetts was running its own risk-adjustment program—is that the use of the statewide premium was arbitrary and capricious. (Hearing Tr. 45:1-5). Plaintiff alleges, and defendants do not dispute, that HHS regulations required Massachusetts to use the statewide average premium, and thus HHS regulations caused its alleged injury. *See* 2014 Proposed Rule, 77 Fed. Reg. at 73,147; 2014 Final Rule, 78 Fed. Reg. at 15,436. Therefore, the only standing challenge the Court need address is defendants' argument that because the relevant Massachusetts agency is not a party and would not be otherwise compelled to make retroactive changes to its rules, any action taken by this Court as to HHS's rulemaking process would not redress plaintiff's harm with respect to that year.[12]

Plaintiff's argument in favor of redressability is that if it prevails here, "it could petition the state for redress under Mass. Gen. Laws ch. 30A, § 4." (Pl. Reply in Supp. Summ. J at 25). That statute provides: "Any interested person may petition an agency requesting the adoption,

[12] Although Massachusetts administered its own risk-adjustment program for the 2015 and 2016 years as well, by that time plaintiff was offering plans in New Hampshire, whose risk-adjustment program was being operated by HHS. Therefore, at a minimum, plaintiff clearly has standing to challenge the 2015 and 2016 rules applied to its New Hampshire plans.

amendment or repeal of any regulation, and may accompany his petition with such data, views and arguments as he thinks pertinent. Each agency shall prescribe by regulation the procedure for the submission, consideration and disposition of such petitions." Mass. Gen. Laws ch. 30A, § 4. Chapter 30A is essentially a state analogue to 5 U.S.C. § 553(e).

Plaintiff, however, cites no authority suggesting that Massachusetts agencies may make retroactive rule changes upon petition—or, for that matter, that this Court could order the agency to do so.[13] Furthermore, the Massachusetts Health Connector, the agency in charge of the Massachusetts risk-adjustment program, has already advised plaintiff in this case that it will not reconsider its methodology for past benefit years. (Am. Compl. Ex. 25 at 5). When plaintiff received the results of the 2014 risk-adjustment calculation requiring it to pay into the program, it challenged that calculation through an administrative procedure available under Massachusetts regulations called a "request for reconsideration." *See* 956 C.M.R. § 13.06. In denying that request, the Health Connector noted that plaintiff was "[i]n essence . . . request[ing] that the Health Connector's risk-adjustment methodology . . . be changed." (Am. Compl. Ex. 25 at 5). The agency stated:

> As discussed above, the Massachusetts methodology was developed by the Health Connector and certified by CMS in advance of the 2014 plan year. Moreover, any change to the methodology would have to published and certified by CMS in advance. Once the methodology is certified, it is relied upon by carriers in predicting risk adjustment's impacts on rate setting and budgeting. A retrospective change in methodology would upset expectations and introduce uncertainty into the market.

(*Id.*).

It is thus true that a ruling in plaintiff's favor from this Court would not directly redress

[13] Like the APA, Massachusetts law defines "regulation" as "the whole or any part of every rule, regulation, standard, or other requirement of general application and *future effect*, including the amendment or repeal thereof." Mass. Gen. Laws. ch. 30A, § 1(5) (emphasis added). This suggests that, like federal regulations, Massachusetts regulations are generally not permitted to have retroactive effect.

its injury with respect to the 2014 benefit year—even with a favorable ruling, it would still have to file a petition with the Health Connector. It seems likely to this Court that such a petition would be futile. Nonetheless, while the Health Connector, as described above, has already denied the relief plaintiff seeks in the context of plaintiff's request for reconsideration, that is not controlling as to how it might respond to a Chapter 30A, § 4 petition—indeed, the Health Connector's response could not have been otherwise, as its regulations specifically prohibit it from considering changes in methodology in connection with requests for reconsideration. 956 C.M.R. § 13.06 ("The risk adjustment methodology cannot be the subject of a request for reconsideration."). And if, as noted, Massachusetts was required by HHS to use the statewide average premiums for the 2014 benefit year, it follows that plaintiff cannot even try to obtain relief in Massachusetts unless it obtains relief here.

Although it is less than clear that plaintiff's alleged 2014 injury—namely, its payment to the Massachusetts risk-adjustment program for the 2014 benefit year—can be redressed by a favorable decision in this lawsuit, that is not the only possible basis for this Court to review the 2014 rule. Because of the way that the rulemaking proceeded here—specifically, the fact that HHS set the rule in 2014 and then declined to substantially change it for at least the 2015 and 2016 benefit years—the Court finds that plaintiff's 2015 injury is sufficient to provide it with standing to challenge the 2014 rule.[14] Put another way, at a minimum, plaintiff suffered injury under the 2015 rule by having to pay 40% of its gross revenue into the New Hampshire risk adjustment pool. The 2015 rule was almost entirely based on the 2014 rule, and therefore in

[14] In each successive proceeding, HHS has explained that the upcoming rule is based on the 2014 rulemaking process. *See* HHS Notice of Benefit and Payment Parameters for 2015, 78 Fed. Reg. 72,322, 72,323-24 (Dec. 2, 2013) ("2015 Proposed Rule") (explaining how the 2015 rule will build on the 2014 rule); 2016 Proposed Rule, 79 Fed. Reg. at 70,676 (explaining how the 2016 rule will build on the 2014 and 2015 rules); HHS Notice of Benefit and Payment Parameters for 2017, 80 Fed. Reg. 75,488, 75,490 (Dec. 2, 2015) ("2017 Proposed Rule") (explaining how the 2017 rule will build on the 2014 methodology).

large part a product of the 2014 rulemaking process. Therefore, to the extent that the 2015 rule was a direct result of the 2014 rulemaking process, the 2014 rulemaking caused plaintiff's injury, and plaintiff's 2015 injury is not redressable without an examination of the 2014 rule. To ignore any challenge to the 2014 rulemaking and take it as a given would be to hold that plaintiff is foreclosed from challenging the parts of the 2015 regulations based on the 2014 process, which includes every challenge it advances in this lawsuit. It cannot be the case that plaintiff, by not offering plans outside of Massachusetts in 2014, is limited to challenging HHS's decision in 2015 not to change the 2014 rule, when the asserted 2015 injury is more than "fairly traceable" to the 2014 rulemaking. Therefore, plaintiff's challenges to the 2014 benefit rule will not be dismissed for lack of standing.

2. Administrative Procedure Act

Plaintiff contends that HHS's risk-adjustment methodology is flawed for multiple reasons. First, it contends that using the statewide average premium as the baseline figure for pricing premiums in the transfer formula unreasonably inflates the charges to issuers with lower prices. Second, it contends that HHS's formula systematically underestimates the costs of insuring members who are not diagnosed with a condition associated with an HCC. Third, it contends that the model misses enrollees who are eligible for HCC classification because (a) until 2018 it did not use prescription-drug data to assign HCCs and (b) until 2017 it did not account for members who were enrolled for a short period of time during which they were not diagnosed. Fourth, it contends that the new risk-adjustment formula has made lower-cost bronze plans economically unviable, in spite of the requirement of the ACA that they be offered.

The response of HHS is that it has taken all of these concerns into consideration and that there are no fatal flaws regarding its methodology. It contends that lower-cost plans such as the bronze plans predominantly sold by plaintiff generally attract healthier enrollees. According to

HHS, plaintiff, with its high percentage of bronze plans, has simply attracted many healthier-than-average enrollees, for which, under the system, it must pay a charge.

Plaintiff's challenges will be taken in turn. Although plaintiff has presented its arguments against all benefit years together, the Court may consider the actions of HHS only with regard to the materials it had before it at the time. The Court will proceed by evaluating whether HHS's initial decisions were arbitrary or capricious in light of the comments and data available in 2014, and then evaluate whether HHS's decisions remained permissible in each successive year as new information was presented to the agency.

a. Use of the Statewide Average Premium

Plaintiff makes two distinct arguments against the use of the statewide average premium: first, that it is contrary to the unambiguous wording of the statute, and second, that it is arbitrary and capricious. The first argument requires a two-step *Chevron* analysis, under which the Court must decide whether the statute is unambiguous and then, if not, whether the agency's interpretation of the statute is reasonable. The second argument requires the Court to determine whether the particular action taken by the agency in these rules violated the APA because it was not the product of reasoned decision-making.

Notwithstanding that analytical distinction, in the context of this case, there is little practical difference between the second *Chevron* step and the APA analysis. *See* 1 RICHARD J. PIERCE JR., ADMINISTRATIVE LAW TREATISE § 7.4, at 604 (5th ed. 2010) ("[T]he question whether an agency engaged in reasoned decision-making within the meaning of *State Farm* often is identical to the question a court must answer under step two of the test announced in *Chevron* . . . ."); *see, e.g.*, *Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011); *Animal Legal Def. Fund, Inc. v. Glickman*, 204 F.3d 229, 234 (D.C. Cir. 2000). Therefore, in the analysis that follows, the Court will treat those two issues together.

Plaintiff first contends that the use of the statewide average premium in the transfer formula is contrary to law because the risk-adjustment statute "unambiguously provide[s] that risk-adjustment assessments cannot be based on factors other than actuarial risk." (Pl. Mem. in Supp. Summ. J. at 16-17). The relevant portion of the statute is sparse: it simply provides that a state shall "assess a charge" if "the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in such State for such year." 42 U.S.C. § 18063(a)(1). It also directs HHS to "establish criteria and methods to be used in carrying out the risk-adjustment activities under this section." 42 U.S.C. § 18063(b).

The basic problem is that under the statute, HHS must both determine "actuarial risk" and assess a "charge." HHS must therefore devise some way to transform a plan's relative "actuarial risk" into a "charge," which necessarily requires establishing "criteria and methods" to convert risk to dollars. Because the statute does not require a particular methodology, it necessarily requires HHS to exercise its discretion in doing so. HHS elected, as a part of its methodology, to use the statewide average premium in the transfer formula. Indeed, even plaintiff does not suggest that HHS should have relied on the risk score alone; rather, it complains that HHS should have used a plan's own premium to scale the risk.[15]

As the statute does not prohibit or discourage HHS from using the statewide average premium in the transfer formula, the question becomes whether HHS's decision to use that premium was reasonable (under *Chevron*) and not arbitrary and capricious (under the APA).

[15] In its reply memorandum, plaintiff shifts its ground somewhat, and contends that while it favors use of a plan's own premium, this Court should focus solely on whether the use of the statewide average premium is proper and leave to the agency the task of determining what to use instead. (Pl. Reply in Supp. Summ. J. at 9 n. 11). But even when identifying possible other alternatives, plaintiff does not suggest that the bare risk score could be used; for example, it suggests medical-claim costs as a possible alternative. And medical-claim costs are not mentioned in the statutory text any more than average premiums are.

HHS's decision to use the statewide average premium was the result of extensive debate. In a white paper published in 2011, the Center for Consumer Information and Insurance Oversight ("CCIIO") proposed four distinct options for establishing a "baseline premium" to use in the risk-adjustment model, and noted the features of each. The two relevant here are the following:

> Option 1a: Weighted State average premiums. This approach would calculate the baseline premium according to the enrollment-weighted average premium in the State. The State average could be calculated with or without adjustment for actuarial value of plans. Using a State average (without actuarial value adjustment) would result in balanced payments and charges, because the State average is a single dollar amount for all plans, and plan risk scores average to 1.0.
>
> . . . .
>
> Option 2: Plan's own premiums. This approach would use each plan's own premiums as the baseline premium. Relative to the prior options, charges would be lowest for low-premium, low-risk plans under this approach, and payments would be highest for high-risk, high-premium plans. In this approach, the amount of charges and payments would be affected by each plan's premium. For plans with a sicker than average risk mix, a lower premium plan would receive less in payments than a higher premium plan, even if the two plans have the same risk level. This could create disincentives for high-risk plans to operate efficiently or set lower prices. Conversely, among two plans with the same healthier than average risk mix, a lower premium plan would have lower charges, potentially creating incentives for low-risk plans to operate more efficiently and/or set lower premiums.

(Def. Mot. For Summ. J. Ex. B at 14-15).

Later in the same paper, HHS presented the results of some modeling experiments estimating the effects of using certain combinations of baseline-premium options and balancing options. Use of the statewide average premium did not require balancing in order to ensure that the charges the program collected could cover the payments due. However, the agency modeled three balancing options in combination with use of a plan's own premium: decreasing payments, increasing charges, and splitting the shortfall by both decreasing payments and increasing charges. (*Id.* Ex. B at 36-37). It concluded that using a plan's own premium with a balancing

strategy that decreased payments would distribute the shortfall "across all the above-average-risk plans in proportion to the risk payment each would have received before balancing" and would cause those plans' premiums to rise. (*Id.* Ex. B at 36). Conversely, using a plan's own premium with a balancing strategy that increased charges would distribute the shortfall among the below-average-risk plans and cause their premiums to rise. (*Id.* Ex. B at 36).

The agency compared the results of using the statewide average premium to using the plan's own premium with "split-the-shortfall" balancing as follows:

> This approach of using weighted State average premiums causes two differences from the plans' own-premium calculation. One is that it disconnects each plan's risk-adjustment compensation from its choice of what premium to charge. Another difference is that the payments and charges now balance. . . .
>
> The weighted State average basis for these calculations has a straightforward effect: those low-risk plans whose premiums are below average will see their charges increase, while high-risk plans with above-average premiums will collect smaller payments. As a result, all eight plans must generate more revenue from premiums. . . . In this way, the result is similar to the "split the shortfall" option shown in Table 2A-3, in which rebalancing was achieved by charging more from the low-risk plans and paying less to the high-risk ones.
>
> Compared to Table 2A-3's "split the shortfall" result, the State average calculations in Table 2B result in greater premium increases among plans whose premiums are far from the State average. . . . On the other hand, plans whose premiums are close to the State average are able to charge premiums that closely approximate their benchmark values.

(*Id.* Ex. B at 37-38).

Then, in the 2014 Proposed Rule, HHS explained:

> In the Risk-Adjustment White Paper, we presented several approaches for calculating risk-adjustment transfers using the State average premium and plans' own premiums. The approaches that used plans' own premiums resulted in unbalanced payment transfers, requiring a balancing adjustment to yield transfers that net to zero. These examples also demonstrated that the balancing adjustments could introduce differences in premiums across plans that were not consistent with features of the plan (for example, [actuarial value] or differences in costs and utilization patterns across rating areas). A balancing adjustment would likely vary from year to year, and could add uncertainty to the rate development process (that is, plan actuaries would need to factor the uncertainty

> of the balancing adjustment into their transfer estimates).
>
> Therefore, we propose a payment-transfer formula that is based on the State average premium for the applicable market, as described in section III.B.3.a. of this proposed rule. The State average premium provides a straightforward and predictable benchmark for estimating transfers. As shown in the examples in the examples in the Risk Adjustment White Paper, transfers net to zero when the State average premium is used as the basis for calculating transfers.
>
> Plan premiums differ from the State average premium due to a variety of factors, such as differences in cost-sharing structure or regional differences in utilization and unit costs. The proposed payment-transfer formula applies a set of cost-factor adjustments to the State average premium so that it will better reflect plan liability. These adjustments to the State average premium result in transfers that compensate plans for liability differences associated with risk selection, while preserving premium differences related to other cost factors described above.

2014 Proposed Rule, 77 Fed. Reg. at 73,139.

> Finally, in the 2014 Final Rule, HHS stated:
>
> The goal of the payment-transfer formula is, to the extent possible, to promote risk-neutral premiums. We agree with commenters that the use of a plan's own premium may cause unintended distortions in transfers. We also believe that both claims and administrative costs include elements of risk selection, and therefore that transfers should be based on the entire premium. We are finalizing our proposal to base the payment transfer formula on the State average premium.

2014 Final Rule, 78 Fed. Reg. at 15,432.

HHS thus considered several options in detail—including the very option plaintiff promotes—before arriving at its conclusion. Ultimately, HHS chose to use the statewide average premium, subject to certain cost-factor adjustments. It did so because it concluded that such an approach would result in balanced transfers, was a "straightforward and predictable benchmark," and would best compensate plans for liability differences due to risk selection, as opposed to other cost factors. Those articulated reasons have a clearly rational connection to HHS's choice. Thus, the record demonstrates that the proposal to use a plan's own premium was actively considered and rejected on rational grounds.

Plaintiff further contends that the statute does not require the risk-adjustment program to

be budget-neutral; that HHS has never explained why the program should be budget-neutral; that even if it did have to be budget-neutral, that would not require the use of the statewide average premium; and that therefore budget-neutrality is "not a legitimate reason to depart from using the issuer's own premium." (Pl. Mem. in Supp. Summ. J. at 23, 36; Hearing Tr. 15:19-20).

Although the statute does not require the program to be budget-neutral, it does not prohibit the program from being budget-neutral, either. Even plaintiff does not argue that the statute forbids budget-neutrality—at most it argues that the statute's silence, when read in conjunction with 42 U.S.C. § 18061(b)(1)(B), which requires the reinsurance program to be budget-neutral, "suggests" that the risk-adjustment program should be operated differently. (Pl. Mem. in Supp. Summ. J. at 24; *see also* Hearing Tr. 12:5-6 ("[T]he risk-adjustment statute doesn't necessarily have to be budget neutral.")).

The question then becomes whether HHS's decision to attempt to operate the risk-adjustment program in a budget-neutral way was unreasonable or arbitrary. It was not. According to HHS, the goal of the program is to spread the risk of insuring unhealthy enrollees among all insurers and eliminate incentives for plans to engage in risk selection. *See, e.g.*, Premium Stabilization Rule, 77 Fed. Reg. at 17,230; 2014 Final Rule, 78 Fed. Reg. at 15,411. The modeling outlined in the 2011 white paper showed that use of a plan's own premium without balancing ran the risk of a shortfall, where there was no money to shore up plans that took on less-healthy patients.[16] The purpose of balancing would be to attempt to spread that

[16] The modeling relied on by HHS apparently never resulted in a system that was unbalanced in the direction of there being *too much* money available for risk adjustment. (*See* Def. Mot. for Summ. J. Ex. B at 35 ("[B]efore accounting for the need to balance payments and charges, the actual premiums will coincide with benchmark values. Plans will set their premiums as if they were expecting their enrollees to have an average level of risk. This is logical, because risk adjustment should remove or add enough revenue to cover nonstandard risk levels, based on each plan's own premiums. However, the results shown here are incomplete as a real-world policy because the risk adjustment payments and charges do not sum to zero; the payments due to high-risk plans are greater than the charges collected from low-risk ones.")).

shortfall around in different ways. But, according to the white paper, reducing payments or increasing charges would disproportionately penalize high- and low-risk plans, respectively, and splitting the shortfall would still fail to cover the payments due to plans with less-healthy members, and therefore still encourage plans to risk-select. (Def. Mot. for Summ. J. Ex. B at 36-38).

Plaintiff suggests that HHS's general appropriations could be used to fund any shortfall, that insurers could sue for the shortfall in the Court of Claims, or that HHS could reduce payments out of the program. But a showing that there are other ways a budget-neutral program *might* have been achieved is not a showing that what HHS actually *did* was unreasonable or arbitrary. The risk-adjustment statute may be reasonably read as intending to level the playing field by spreading the risk among insurers, not by having the government subsidize the costs of insuring less-healthy people through HHS's general appropriations budget or the Judgment Fund.

Furthermore, as HHS points out, the risk-adjustment program was meant to be run by the states. Congress could not, under the Constitution, require the states to use their own money to fund a federal program. *See Printz v. United States*, 521 U.S. 898, 929-30 (1997); *New York v. United States*, 505 U.S. 144, 175-76 (1992). It therefore stands to reason that absent any appropriation, Congress expected the states to run budget-neutral risk-adjustment programs, and for HHS to set its federal regulations to allow it to certify such programs. *See* 45 C.F.R. § 153.310. It was not unreasonable or arbitrary for HHS to attempt to design the program to pay for itself, as opposed to exposing its own general appropriations to float the program for any state that chose not to run its own program. Nor was it unreasonable or arbitrary to implement the program in such a way as to avoid having the participants sue annually in federal court for the program to function.

To the extent that plaintiff complains that HHS did not adequately explain its decision to run the program in a budget-neutral way, the claim must likewise fail. There is no evidence that there was any significant comment on the topic that HHS was required to address in 2014. In any event, as set forth in the 2011 white paper, HHS considered the effects of non-budget-neutral methodologies and rationally chose to operate a budget-neutral program. Therefore, HHS's decision to use the statewide average premium in the risk-adjustment formula was not contrary to law, unreasonable, or arbitrary or capricious.

Plaintiff also attacks the stated rationale that using the statewide average premium is a "straightforward and predictable benchmark" on the ground that, for smaller issuers, the average premium is a "black box." (Pl. Mem. in Supp. Summ. J. at 27). But, assuming that it is reasonable to operate the program in a budget-neutral way, plaintiff's proposal appears to be even less predictable. Under plaintiff's proposal, a plan—knowing its own premium and its own risk pool—presumably would be able to predict how much it would owe or receive under the transfer formula. But even if HHS adopted a particular methodology for addressing any shortfall in advance, the plan would have no way of ascertaining the results of the balancing calculation without knowing the enrollment, risk, and premium data for every other plan in the state. *See* 2014 Proposed Rule, 77 Fed. Reg. at 73,139 ("A balancing adjustment would likely vary from year to year, and could add uncertainty to the rate development process (that is, plan actuaries would need to factor the uncertainty of the balancing adjustment into their transfer estimates)."). Thus, compared to any of the other methodologies HHS was considering, using the statewide average premium appeared to be at least somewhat predictable, because the only piece of the formula issuers are left to guess when setting their rates is what the statewide average premium

will be.[17] Relative predictability is therefore a rational reason for HHS to use the statewide average premium as a baseline in its transfer formula.

Plaintiff further complains that HHS's statement that using a plan's own premium would cause "unintended distortions in transfers" is vague and unsupported, and therefore does not meet its obligation to engage in reasoned decision-making. 2014 Final Rule, 78 Fed. Reg. at 15,432. But the Court finds that HHS's meaning here may be "reasonably discerned" from the record. *Bowman Transp.*, 419 U.S. at 286. Specifically, HHS explained in the white paper that "[f]or plans with a sicker than average risk mix, a lower premium plan would receive less in payments than a higher premium plan, even if the two plans have the same risk level. This could create disincentives for high-risk plans to operate efficiently or set lower prices." (Def. Mot. for Summ. J. Ex. B at 14-15). HHS also explained that using the average premium "disconnects each plan's risk-adjustment compensation from its choice of what premium to charge." (*Id.* Ex. B at 37-38). It seems clear that HHS was concerned that issuers would price their plans to game the risk-adjustment calculation or that individual plans' pricing decisions could have an outsize effect on the total funds available or required for the risk-adjustment program in a given year. In any event, the other reasons HHS gave for choosing the statewide average premium are sufficient to show that it considered the relevant comments and rationally chose to use the average premium based on the evidence before it.

[17] And plans have a reasonable possibility of doing that because (1) they will know who the big issuers are and what they have charged in the past, and (2) they have a grace period to adjust after rates are first published if their guess turns out to be substantially incorrect. (Def. Reply in Supp. Summ. J. at 9 n.6 & Exs. E & F). Furthermore, plaintiff does not really contend that issuers were surprised by the risk-adjustment payments because the statewide average premiums turned out to be different from what they anticipated—rather, it seems that the problem was that their plan's average risk score was much lower than they expected it to be. (*See* Pl. Mem. in Supp. Summ. J. Ex. 10 ¶ 56 (declaring that plaintiff priced as if its risk adjustment would be zero, assuming it would attract an average risk pool, when in fact it attracted a healthier-than-average risk pool); *see also* Hearing Tr. 67:7-21)).

Finally, plaintiff complains that use of the statewide average premium affords issuers with dominant market positions too much control, allowing those issuers to punish smaller issuers who have found ways to keep costs down and charge less, and thus perversely rewards price-increasing behavior. However, plaintiff has not cited to any materials before the agency in the 2014 rulemaking process that show the catastrophic consequences plaintiff asserts occurred or would occur—all those materials are from later rulemaking processes. Plaintiff points to the 2011 white paper as evidence that HHS knew that using the statewide average premium would penalize low-priced issuers and drive up premiums. But that paper shows that unless balancing is abandoned, premiums rise in every scenario—just for different segments of the market. (Def. Mot. for Summ. J. Ex. B at 35-38). According to the paper, using the statewide average premium would ensure that (1) the costs of insuring plans with less-healthy members are neutralized and (2) all plans share that cost, as envisioned by Congress in creating the program. It is true that, compared to using a plan's own premium and balancing by splitting the shortfall, the use of the statewide average premium causes greater premium increases for plans whose benchmark premiums (premiums priced to cost without risk adjustment) are farther from the mean. But the existence and acknowledgment of a disadvantage of a particular policy is not enough for this Court to overturn that policy. It is for HHS to weigh the options, and this Court cannot substitute its judgment for that of the agency, absent an arbitrary or irrational choice. There were documented advantages and disadvantages to both options, and it was rational for HHS to decide that the increased predictability of the statewide average premium outweighed any harm to very low-cost plans.[18]

[18] Nor are the allegedly disastrous effects of using the statewide average premium so apparent that HHS should be deemed to have been able to anticipate them. Rather, plaintiff's argument that the methodology punishes efficiency fails to address the other side of the coin: to the extent that use of the statewide average premium tends to inflate the charges to low-risk, low-cost plans, it will also inflate the payments to high-risk, low-cost plans. Thus,

For the 2017 benefit year, HHS received multiple comments protesting the use of the statewide average premium. (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 6-7 (Minuteman 2017 Comment); *Id.* Ex. M-18 at 3 (New Mexico Health Connections 2017 Comment); *Id.* Ex. M-21 at 2 (Evergreen Health 2017 Comment); *Id.* Ex. M-24 at 5 (Land of Lincoln Health 2017 Comment)). HHS responded, "We did not propose changes to the transfer formula, and therefore, are not addressing comments that are outside the scope of this rulemaking." 2017 Final Rule, 81 Fed. Reg. at 12,230.

That response is at least somewhat troublesome in this context. By 2017, the use of statewide average premium had apparently resulted in serious problems, and it might have been prudent for HHS to address those comments directly. At some point, if an agency's rules have become obviously unreasonable or unworkable, the agency surely has some obligation to reconsider its actions, or at least respond to comments pointing out that fact, even if technically outside the scope of its proposed rulemaking. *See Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 549 (D.C. Cir. 1997) (suggesting that agencies are not required to address comments outside the scope of the rulemaking as long as they do not cast doubt on the reasonableness of the agency's position); *Sherley v. Sebelius*, 776 F. Supp. 2d 1, 22 (D.D.C. 2011) (same).

In this case, however, HHS had already considered alternatives to using the statewide average premium, and the comments at issue did not raise any concerns that HHS had not considered before; they merely pointed out that a plan whose premiums are well below a state's average will find that its risk-adjustment charge is inflated. HHS was aware of that aspect of its

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the policy does not, as plaintiff claims, deliberately punish low-cost plans—it incentivizes plans to cut costs only to the extent that they can do so while avoiding risk selection.

methodology at least as early as 2011, and had decided that other considerations prevailed to justify its choice. (Def. Mot. for Summ. J. Ex. B at 38 ("Compared to Table 2A-3's "split the shortfall result, the State average calculations in Table 2B result in greater premium increases among plans whose premiums are far from the State average. . . . On the other hand, plans whose premiums are close to the State average are able to charge premiums that closely approximate their benchmark values.")).

For the reasons discussed above, it was not unreasonable or irrational for HHS to use the statewide average premium in the first instance. Because the 2017 comments raised nothing new, HHS was not required to re-justify its choice. Therefore, the continued use of the statewide average premium was not arbitrary or unreasonable under the circumstances.

b. Underestimation of Cost of Enrollees Without an HCC

Plaintiff further contends that the HHS transfer formula underestimates the cost of healthier enrollees who do not qualify for an HCC. Under the HHS formula, those enrollees will receive an individual risk score based only on their age and sex. But, plaintiff argues, they may still consume health care (for example, if they use preventative care services, experience a catastrophic injury, suffer from chronic low back pain, need joint replacement surgery, or become at risk for developing a condition covered by an HCC code and undergo aggressive clinical therapy to prevent that illness). (Pl. Mem. in Supp. Summ. J. at 34-35). Plaintiff contends that "[f]or these reasons, the HHS formula underestimates health care costs for enrollees without an HCC by 10%-35%," and that accordingly, to the extent that premiums from healthy members are being paid out for such care, those funds are not available to offset payments made either within the plan to predictably sicker enrollees or in risk-adjustment

transfers to other plans with predictably sicker enrollees. (*Id.* at 35).[19]

The Court finds it difficult to discern from the briefing precisely what feature of the transfer formula plaintiff is complaining about. Clearly, plaintiff takes issue with the *result* that premiums from healthier enrollees are not balancing out losses from sicker enrollees. But, in explaining why that is, plaintiff mostly points to the possibility of random, expensive events that could happen to any enrollee, regardless of his or her overall health. Although the Court understands the point that plans may spend money on otherwise healthy enrollees with bad luck, the Court does not see that plaintiff is suggesting that risk adjustment should incorporate HCCs for random events.[20] The only other cost that plaintiff identifies as contributing to the undercompensation problem is the use of preventative services. Although plaintiff does not say so, its complaint appears to be that the transfer formula treats expenses that are more or less the same for everyone as differing depending on risk score; therefore, plans with healthier members are overcharged while plans with less-healthy members are overpaid.

Plaintiff points to only one comment for the 2014 benefit year related to the issue of undercompensating plans for enrollees without HCCs, which was from the Blue Cross Blue Shield Association ("BCBSA"). (Pl. Reply in Supp. Summ. J. Ex. M-1 (submitted Apr. 30,

[19] Note that HHS's formula does not "estimate health care costs" for any enrollee—it ultimately estimates the *relative* cost of insuring enrollees of varying health status. The Court interprets plaintiff's complaint as being that the transfer formula underestimates the cost of insuring enrollees without HCCs relative to the cost of insuring enrollees with HCCs.

[20] HHS has been clear from the beginning that risk adjustment is not meant to redistribute that kind of ordinary insurance risk—only the risk associated with *predictably* less-healthy enrollees among whom insurers might be incentivized to risk select. (*See* Def. Mot. for Summ. J. Ex. B at 6 (explaining that "some types of health care expenses are random (for example, those due to an accident)"; that a model "excluding such conditions" would ensure that "risk adjustment does not remove the insurance risk from spending due to unforeseen events"; and that the goal of risk adjustment was to "recognize[] the costs of medical conditions that are predictable to the enrollee and could influence enrollment decisions")); 2014 Proposed Rule, 77 Fed. Reg. at 73,129 (explaining that HHS selected HHCs for inclusion in the model in part based on "[w]hether the HCC identifies chronic or systematic conditions that represent insurance risk selection or risk segmentation, rather than random acute events"). To the extent plaintiff is arguing that HHS should have included HCCs for random events, it was reasonable for HHS to decline to do so, for those reasons.

2013)). That comment in fact postdated the 2014 Final Rule—it was submitted in response to a proposed interim rule addressing certain amendments to the 2014 rule relating to risk corridors and cost-sharing reductions. (*Id.*); *see* Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 15,541 (Mar. 11, 2013) (Interim Final Rule with Comment).[21] The 2014 Final Rule, however, indicates that some commenter might have timely raised this issue, or something like it. It states: "One commenter suggested that we use net claims, or approximate net claims by using 90 percent of the State average premium, as the basis for risk-adjustment transfers." 2014 Final Rule, 78 Fed. Reg. at 15,432. HHS responded that it "believe[d] that both claims and administrative costs include elements of risk selection, and therefore, that transfers should be based on the entire premium." *Id.*

It is not at all clear that the potential problem of undercompensating for members without HCCs was raised to HHS in in the notice-and-comment period for the rule finalizing the risk-adjustment transfer formula for 2014.[22] In the absence of a specific stated concern, there was no reason to believe that HHS's formula would be biased in this way—it used a database of past

[21] The April 2013 BSBCA comment recommended that HHS base the risk-adjustment transfer only on the part of the statewide average premium representing claims and claim-adjudication expenses because its "testing of the risk-adjustment methodology indicate[d] that it over-compensates issuers for members with HCCs, while under-compensating issue[r]s for members without HCCs." (Pl. Reply in Supp. Summ. J. Ex. M-1 at 4307 (submitted Apr. 30, 2013)). It explains that "Members without HCCs can still incur claims, want access to wellness information, and need customer service. Additionally, other administrative expenses apply to all members such as billing, the reinsurance-contribution fee, exchange-use fees, and taxes." (*Id.*).

Note that the BCBSA's comment to the 2014 proposed rule, submitted on December 28, 2012, says the opposite (albeit in the reinsurance context): "[D]ue to the imperfect correlation of risk scores to actual health-care expenses, BCBSA does not believe that over-compensation for high-risk individuals will occur. Generally, risk-adjustment models tend to underestimate costs for high-risk claimants and therefore, in our opinion, it is unlikely that reinsurance payments will result in overcompensation." (Def. Reply in Supp. Summ. J. Ex. K at 52).

[22] BCBSA's comment on the 2014 Proposed Rule did not identify undercompensation for healthy enrollees as a problem. (*See* A.R. 3047-113). Nor did it request that HHS use 90% of the statewide average premium in the formula; in response to HHS's notice that it would use the statewide average premium as the basis to calculate risk-adjustment transfers, BCBSA wrote: "BCBSA supports this proposal. We believe it would be more appropriate to base risk-adjustment transfers on claim cost plus adjudication expense, but understand the simplicity inherent in the state average premium baseline." (A.R. 3099).

health costs to develop the age and sex factors, which presumably accounted for things such as random events and preventive care (at least, relative to other subpopulations). *See* 2014 Proposed Rule, 77 Fed. Reg. at 73,127, 73,129-31. HHS's statistical tests determined that the predictive power of its model was "within published ranges for concurrent models." 2014 Final Rule, 78 Fed. Reg. at 15,420. And HHS points to record materials showing that, in fact, the prevailing view was that risk-adjustment transfer formulas systematically *overcompensate* for healthy enrollees. (Def. Reply in Supp. Summ. J. Ex. J at 24; *id.* Ex. K at 52; *id.* Ex. L at 12). Therefore, HHS's transfer formula was not arbitrary or capricious in 2014 simply because it did not explicitly account for administrative costs or preventive care, or because it did not anticipate that its formula would be biased against healthy enrollees for some other, unspecified reason.

For the 2017 benefit year, HHS proposed to recalibrate the risk-adjustment model by recalculating the weights assigned to various HCCs and demographic factors using more recent data and incorporating preventive services in its simulation of plan liability. 2017 Proposed Rule, 80 Fed. Reg. at 75,499. The proposal explained that HHS would identify claims related to preventive care in the model data sets and then "adjust[] plan liability by adding 100 percent of preventive services covered charges to simulate plan liability for all metal levels" so that the "[t]otal adjusted simulated plan liability is the sum of preventive-services covered charges, and non-preventive services simulated plan liability." *Id.* Comparing the new model to the old one, HHS found that "[a]djusting for preventive services increases age-sex coefficients relative to HCC coefficients, especially in the higher cost-sharing metal tiers (bronze and silver), and in age/sex ranges with high preventive-services expenditures (for example, young adult females)." *Id.* HHS predicted that "the risk scores of healthy enrollees (whose risk scores are based solely on model age-sex coefficients) will likely rise relative to the risk scores of the less healthy

(whose risk scores include one or more HCC coefficients in addition to an age-sex coefficient), especially in bronze and silver plans." *Id.*

Plaintiff points to three comments HHS received related to this topic in 2017. (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 4-5 (Minuteman 2017 Comment); *Id.* Ex. M-18 at 2 (New Mexico Health Connections 2017 Comment); *Id.* Ex. M-30 at 8487, 8489 (Health New England 2017 Comment)). All three comments pointed out that the risk-adjustment transfer formula undercompensates plans for enrollees without HCCs while overcompensating for enrollees with HCCs. And they all attached the same November 4, 2015 white paper written by Consumers for Health Options, Insurance Coverage in Exchanges in States ("CHOICES"). (*See* Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 2).

In response, HHS finalized its proposal to include preventive services in the plan-liability simulation. 2017 Final Rule, 81 Fed. Reg. at 12,206. It explained: "We have attempted to address the range between enrollees without HCCs and those with HCCs by finalizing the incorporation of preventive services into our simulation of plan liability. While overall this is not a very large effect, it does have a noticeable effect on certain demographic subgroups, resulting in more accurate payments for enrollees without HCCs." *Id.* at 12,218.

Plaintiff basically complains that HHS did not do enough to address the problem. But apart from plaintiff's general assertion in its comment that the "changes proposed . . . while useful, are completely insufficient to mitigate the extreme dysfunction that risk adjustment has introduced into the market," (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 5), it points to no evidence in the record to suggest that incorporation of preventive-care costs would not address the particular concern that the risk-adjustment formula undercompensated for healthy enrollees. In its brief, plaintiff argues that HHS's response in the final rule—that the "overall" effect was

"not very large"—is an admission that it did not do enough. But HHS had explained in the proposed rule that inclusion of preventive care would alleviate this bias in the very population plaintiff complains about—members without HCCs in higher-cost-sharing metal tiers—and the final rule's statement that "it does have a noticeable effect on certain demographic subgroups, resulting in more accurate payments for enrollees without HCCs" is a statement that HHS understood it had addressed the concerns raised in the comments.[23]

Furthermore, even plaintiff's own comment proposed only "short-term solutions" to stabilize premiums while "HHS convenes the appropriate experts to reexamine the methodology and make appropriate changes to mitigate unintended consequences." (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 7). None of those short-term proposals were specific to the problem of bias against non-HCC enrollees, and it seems that the source of this bias was not well understood (and apparently still is not, as plaintiff's brief does not satisfactorily explain how the formula should have been different). (*See id.* Ex. M-25 pt. 1 at 6-7).[24] Indeed, the CHOICES white paper plaintiff attached to that comment—and which was attached to all the other

[23] A 2017 comment from Anthem stated: "Anthem actuaries analyzed the proposed weights and have determined that the proposal does not resolve our concerns about the unbalanced incentives for members with HCC diagnoses and the deterioration of the market-wide risk pool. While the demographic factors do increase for catastrophic plans and for females within bronze plans, the impact of this change is relatively small. This proposed update does little to change the relative value of HCC members to non-HCC members." (Pl. Reply in Supp. Summ. J. Ex. M-16 at MH1528-29). While this comment also criticizes HHS for doing too little, it supports HHS's evaluation of the specific impacts of the change and does not suggest any possible solutions.

[24] The comments of plaintiff and Health New England proposed incorporating prescription-drug data, which would help capture more people who have HCCs, but would not fix any bias in the formula against those who truly are not eligible for HCCs. (Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 4-5 ("We also support HHS's proposition to incorporate preventive services into its simulation of plan liability, however we feel even more can be done to enrich the calculation of HCC risk scores. By basing the calculation on more factors and incorporating . . . preventive-services and prescription data . . . the HCC score will more accurately account for members' medical utilization."); *Id.* Ex. M-30 at 8489 ("The understatement of costs for individuals with zero HCCs (and corresponding overstatement of costs for individuals with one or more HCCs) should be eliminated. The proposals to allow use of pharmacy claims and to take into account preventive care are steps that should move in the right direction for this concern.")). HHS's failure to incorporate prescription-drug data is another of plaintiff's complaints, and is addressed below.

comments addressing the issue—explained that the tendency of HHS's formula to underestimate the relative cost for enrollees without HCCs

> counterintuitively, is the opposite of what normally occurs in risk-adjustment models developed in the private sector and the CMS-HCC model for Medicare Advantage enrollees. As a general rule, risk-adjustment models can only explain a portion—often a fairly low one—of the total statistical variation that exists across individuals' or groups' health care costs. Cost variation that is not attributed to the model's demographic, diagnosis, and other explanatory variables is normally reflected in the model's baseline cost level, causing it to be higher than would be the case with greater explanatory power among the variables. Correspondingly, the demographic and non-demographic coefficients in most models tend to understate the actual cost variation attributable to these factors.
>
> It is not clear why the HHS-HCC risk-adjustment model understates costs for individuals without HCC diagnoses and overstates costs for those who have diagnoses, in contrast to virtually all other risk-adjustment models.

(Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 2 at 4). Because it was not clear why the formula was biased the way it was, it was not unreasonable for HHS to proceed cautiously, and not simply adopt a short-term fix.

Finally, plaintiff argues that HHS's modification of the transfer formula to include preventive care (and, beginning in 2018, administrative costs) is an admission that the prior-year formulas were erroneous, and therefore HHS should have made retroactive changes to the formula for those years. But, as explained above, HHS is generally prohibited from retroactive rulemaking, and could not spontaneously change its prior-year formulas. Furthermore, an adjustment to a rule, made with the benefit of results from 2014 is *not* an "admission," or conclusive evidence, that the prior rule was arbitrary or capricious at the time it was made. The 2014 rule was not arbitrary or capricious, in light of the information available at the time.[25]

[25] Plaintiff complains that HHS ignored a white paper by former CMS Chief Actuary Rick Foster that calculated the amounts by which the costs for a person without an HCC were off and offered a correcting factor for HHS to use. Because this paper was not before the agency during the rulemakings at issue here, the Court need not address it.

c. Failure to Capture HCC Status

Next, plaintiff argues that the transfer formula fails to adequately assign HCCs to all eligible enrollees, with the result that certain plans appear to cover healthier populations than they actually do. Plaintiff identifies two specific deficiencies: first, that HHS's plan fails to account for partial-year enrollment, and second, that it ignores prescription-drug-utilization data.

i. Failure to Account for Partial-Year Enrollment

In order to qualify for an HCC, an enrollee must be diagnosed with an HCC-qualifying condition during the time he or she is enrolled in the plan. *See* 2014 Proposed Rule, 77 Fed. Reg. at 73,127-28 (explaining the concurrent model). Plaintiff complains that when members switch plans part way through the year, the second plan may pay out for things related to that enrollee's diagnosis, but may not be credited with that enrollee's HCC if the enrollee does not visit a doctor during the part of the year he or she is enrolled in the second plan. Plaintiff also argues that the formula's calculation of risk on a per-month basis inappropriately spreads the costs of insuring a patient throughout the year, when in fact plans may incur the full amount of liability for a patient with an HCC in only a few months of enrollment. (To use a simple example, a woman could be only enrolled for two months, during which she gives birth and incurs high medical costs).

Plaintiff points to one comment in the 2014 rulemaking process concerning this topic. The Association for Community Affiliate Plans commented that "newly insured individuals lack the diagnostic records needed for effective risk adjustment," and that enrollees who "move between sources of insurance coverage due to changes in eligibility" will "limit the availability of diagnoses needed for risk adjustment." (Pl. Reply in Supp. Summ. J. Ex. M-8 at i). The comment further stated that "[t]he challenges of the newly insured and churn [that is, movement between plans] will be mitigated by the temporary use of reinsurance and risk corridors. But in

2017 when these supports are discontinued, risk adjustment alone will bear more fully the burden of getting the rates right. As a result, plans and public officials should devote time and resources to improving the risk-adjustment system to ensure accurate payments to plans with disproportionate shares of high-need enrollees." (*Id.* Ex. M-8 at ii). It suggested that "[s]hortening the window of time required for diagnostic information to be used in risk adjustment for new members could alleviate this problem. Proponents of concurrent risk adjustment might suggest a window as short as three months." (*Id.* Ex. M-8 at 6; *see id.* Ex. M-8 at 7 (advocating a concurrent methodology)). And it acknowledged that "[a] concurrent approach will somewhat improve the ability to produce more accurate risk scores for plans enrolling newly insured members and those who churn, who may have pent-up demand for health care and lack established diagnostic records." (*Id.* Ex. M-8 at 2).

The HHS commentary to the 2014 Proposed Rule acknowledged that partial-year enrollment might be a problem. HHS explained that it was using a concurrent model because "we anticipate that enrollees may move between plans, or between programs. A concurrent model would be better able to handle changes in enrollment than a prospective model because individuals newly enrolling in health plans may not have prior data available that can be used in risk adjustment." 2014 Proposed Rule, 77 Fed. Reg. at 73,128.

The 2014 Final Rule shows that HHS continued to consider methods of addressing the partial-year-enrollment concern. It reiterated its reasoning in favor of the concurrent model, and further stated:

> Our models were calibrated to account for short-term enrollment in several ways. First, enrollee diagnoses were included from the time of enrollment. Also, in the statistical estimation strategy for the HHS HCCs, average monthly expenditures were defined as the enrollee's expenditures for the enrollment period divided by the number of enrollment months, annualized expenditures (plan liability) were defined as average monthly expenditures multiplied by 12, and regressions were

> weighted by months of enrollment divided by 12. We believe that this statistical strategy, alongside the minimum enrollment requirement, ensures that monthly expenditures are correctly estimated for all individuals.

2014 Final Rule, 78 Fed. Reg. at 15,420, 15,421.

Plaintiff does not identify a specific recommendation that HHS should have adopted to fix the partial-year-enrollment problem, apart from the use of prescription-drug data, discussed below. The single comment identified by plaintiff suggested only (1) shortening the minimum length of enrollment required for an enrollee before diagnostic information can be considered by the risk-adjustment formula and (2) using a concurrent approach, both of which HHS's formula did. While plaintiff complains that HHS's monthly formula in fact exacerbates the partial-year enrollment problem, it does not suggest how HHS should have assigned risk to partial-year enrollees without calculating risk on a per-month basis. In any event, the record reflects that HHS considered this problem in 2014, considered the comment discussing it, and chose to address it with certain features of its transfer formula. That choice, under the circumstances, cannot be characterized as arbitrary or unreasonable.

In the 2017 Proposed Rule, HHS sought comments on how to make its formula more predictive for partial-year enrollees.

> [W]e would like to explore the effect of partial-year enrollment in the HHS risk-adjustment methodology. We have received input that issuers are experiencing higher than expected claims costs for partial-year enrollees. We have also received input that the methodology does not capture enrollees with chronic conditions who may not have accumulated diagnoses in their partial year enrollment. At the same time, as compared to full-year enrollees of the same relative risk, partial-year enrollees are less likely to have spending that exceeds the deductible or annual limitation on cost sharing.

2017 Proposed Rule, 80 Fed. Reg. at 75,500. Several comments were submitted in response. (*E.g.*, Pl. Reply in Supp. Summ. J. Ex. M-29 at MH1564-65). HHS gave a detailed summary of those comments and their varied proposed solutions in its final rule. 2017 Final Rule, 81 Fed.

Reg. at 12,220. HHS noted: "We appreciate commenters' substantive feedback on accounting for partial-year enrollment in future recalibrations and will continue to analyze this issue and include our findings in the White Paper for discussion at the March 31, 2016 risk-adjustment conference." *Id.*

HHS did exactly that, devoting several pages of analysis to that topic in its white paper. (Def. Mot. for Summ. J. Ex. C at 35-39). That paper presented results from several modeling simulations exploring the effects of adopting various solutions, and explained the steps HHS was taking to evaluate the feasibility of those options (and possible combinations of options). (*Id.*). After reviewing the feedback from the white paper, HHS announced on June 8, 2016, that "[it] intended to propose that, beginning for the 2017 benefit year, the risk adjustment model include adjustment factors for partial year enrollees." 2018 Final Rule, 81 Fed. Reg. at 94,072. It then finalized that adjustment, beginning for the 2017 benefit year, in the 2018 Final Rule. *Id.*

Plaintiff complains that HHS's "repeated failure to consider the problems and solutions raised by commenters constitutes arbitrary and capricious conduct." (Pl. Mem. in Supp. Summ. J. at 41). But the record shows that HHS did consider those comments, determined that further investigation of possible solutions was necessary, and engaged in that further investigation. Again, that response was not arbitrary or capricious.

Plaintiff also suggests that HHS did not move fast enough to rectify the problem. HHS finally calculated the results of the 2014-benefit-year risk transfers at the end of June 2015. It proposed the 2017 benefit rule in December 2015 and finalized it in March 2016. Weeks later it produced a white paper detailing proposed model simulations to fix the problem going forward. It seems clear from that timeline—and the fact that HHS requested comments in the 2017 proposed rule on possible *future* solutions to the partial-enrollment problem—that HHS was not

ready with a specific proposed solution in December 2015. With such a complicated program to administer, and no evidence that there was a patently apparent, ready-made solution that could be predictably incorporated with all the other moving parts of the model, it was not arbitrary or capricious for HHS take more time and hold a public meeting, especially as it was ultimately able to implement the changes in the 2017 benefit year.

ii. Use of Prescription-Drug Data to Calculate Risk

Plaintiff also complains that because enrollees do not always receive a documented HCC diagnosis during their enrollment periods, it was arbitrary and capricious for HHS not to use prescription-drug data to determine whether an enrollee has an HCC-qualifying condition. Plaintiff argues that using prescription-drug data is more reliable and efficient than using claims data, and points to several comments in the 2014 rulemaking supporting use of such data.

HHS did consider using prescription-drug data to assign HCCs from the very beginning of the process, but consistently expressed concern that doing so would incentivize doctors to over-prescribe medications. Its 2011 white paper noted that "[i]ncluding prescription data in a risk-adjustment model . . . could offer powerful incentives to steer treatment toward pharmaceutical therapy in order to identify risk of the enrolled population." (Def. Mot. for Summ. J. Ex. B at 9). HHS's proposed rule for 2014 explained:

> At this time, we have elected not to include prescription drug use as a predictor in each HHS risk-adjustment model. While use of particular prescription drugs may be useful for predicting expenditures, we believe that inclusion of prescription-drug information could create adverse incentives to modify discretionary prescribing. We seek comments on possible approaches for future versions of the model to include prescription-drug information while avoiding adverse incentives.

2014 Proposed Rule, 77 Fed. Reg. at 73,128. The final rule provided: "HHS is finalizing its proposal to exclude prescription drugs for the initial HHS risk-adjustment models, but will consider how prescription drugs could be included in future HHS risk-adjustment models." 78

Fed. Reg. 15,419.

Plaintiff argues that strategic prescribing behavior is not a genuine concern and therefore it was not a rational basis to reject using prescription data. (Pl. Reply in Supp. Summ. J. at 20-21; Hearing Tr. 34:3-36:9). But the record before the agency included a report on the use of pharmacy data from RTI International, a consulting firm hired to help HHS research issues related to implementing the ACA. That report determined that "[t]he most salient concern with tying risk-adjustment payments to drug usage is the likely distortion of provider decisions toward pharmaceutical therapies. This distortion would create real costs: not only the costs for of [sic] the drugs themselves, but also the health outcomes that would be diminished by any deviation from clinical best practices." (Def. Mot. for Summ. J. Ex. D at 4). It cited a study in support of that conclusion, and explained how the incentives are worst for cheap drugs with higher risk-adjustment payments, and can penalize doctors for cost-effective prescribing habits. (*Id.*). It explained how other health systems that use pharmacy data have attempted to avoid this problem, but warns that "a model that relies on drug data will need to be carefully specified," because while "[b]ad incentives and gaming can be avoided, for example, by including only those drugs and therapeutic classes for which there is nearly universal clinical agreement about their use," such a system "poses a big challenge to the model design . . . because there's no clear line where agreement becomes widespread enough to be considered 'universal,' and the cases where this occurs are likely to be rare." (*Id.* Ex. D at 4-5). In light of that evidence before the agency, it was not arbitrary or capricious for HHS to be concerned about prescribing incentives. Furthermore, the APA does not require HHS to have chosen the best solution; it need only have considered significant comments and articulated a rational connection between the facts found

and the choice made. HHS satisfied that requirement here.[26]

After 2014, HHS continued to seek comments on and investigate the feasibility of including prescription-drug data in its risk-adjustment model.

> [W]e are evaluating how we may incorporate prescription-drug data in the Federally certified risk-adjustment methodology that HHS uses when it operates risk adjustment. Prescription-drug data could be used in the risk-adjustment methodology to supplement diagnostic data by using the prescription-drug data as a severity indicator, or as a proxy for diagnoses is in [sic] cases where diagnostic data are likely to be incomplete. We are assessing these approaches, with particular sensitivity to reliability and the potential for strategic behavior with respect to prescribing behavior. As we noted in the 2014 Payment Notice, we did not include prescription drugs to predict expenditures to avoid creating adverse incentives to modify discretionary prescribing. We are evaluating whether we can improve the models' predictive power through the incorporation of prescription drugs without unduly incentivizing altered prescribing behavior.

2017 Proposed Rule, 80 Fed. Reg. at 75,499-500. As with the partial-year-enrollment issue, the 2017 Final Rule extensively summarized the many comments submitted on the topic (at least one of which supported implementation only after a separate notice-and-comment process specifying the methodology in detail) and promised to "explore the incorporation of prescription drugs in the risk-adjustment model in the White Paper and at the conference in March 2016." 2017 Final Rule, 81 Fed. Reg. at 12,219. HHS stated:

> We agree with commenters that prescription drugs have the potential to increase the predictive power of the risk-adjustment models. We agree that different prescription drugs will likely be more or less predictive depending on the condition. We also remain cautious about creating incentives to modify discretionary prescribing to artificially increase the severity of diagnoses.

Id. at 12,219-20.

[26] While not mentioned by HHS in the 2014 Final Rule itself, the record contains many additional reasons not to use prescription-drug data. For example, the 2011 white paper noted that "clinical indications for a given pharmaceutical may change over time, prompting the need for more frequent modifications to the risk-adjustment model than if pharmaceutical data were not used." (Def. Mot. for Summ. J. Ex. B at 10). The RTI paper explained that "drug usage can be a biased indicator of health status" because "populations with better adherence to drug therapies," (typically, wealthier and better-educated populations) "will appear sicker." (Def. Mot. for Summ. J. Ex. D at 5).

As promised, the 2016 white paper addressed this topic in considerable detail. In thirty single-spaced pages, HHS outlined the benefits and concerns associated with including prescription-drug data, provided a framework for analyzing that data, proposed a classification system, presented an illustrative model, and evaluated the results of that model. (Def. Mot. for Summ. J. Ex. C at 40-70). Having received comments on that approach, HHS subsequently included some prescription-drug data in its model for the 2018 benefit year. 81 Fed. Reg. at 94,074-80.

HHS's decision to leave prescription-drug data out of the 2017 rule and consider the matter further was not unreasonable. Plaintiff points to a variety of comments extolling the virtues of such data. (*See* Pl. Reply in Supp. Summ. J. Ex. M-25 pt. 1 at 4; *id.* Ex. M-27 at 5). But HHS's concerns about using it remained valid (and, as evidenced by the detailed 2016 white paper, included more than just the risk of gaming). HHS showed that it was open to using such data and was actively considering the change. It was not required to re-justify its position in response to every comment.

As with the preventive-care changes, the fact that HHS ultimately included prescription-drug data in its model is not evidence that its prior model was arbitrary and capricious. Rather, it shows that the agency was appropriately responsive to concerns and willing to refine its model as the results of its past performance became available.

d. Discrimination Against Bronze Plans

Plaintiff's final challenge is that HHS's transfer formula unfairly discriminates against bronze plans. The crux of the challenge is that the collection of flaws it identified in this lawsuit resulted in a formula that disproportionately harmed bronze plans to the point of driving them out of business. That result, according to plaintiff, must be illegal, because the ACA clearly intended consumers to have the option of choosing bronze plans. *See* 42 U.S.C.

§ 18022(d)(1)(A).

Plaintiff acknowledges that this issue was not raised before the agency in the 2014-2017 benefit years. (Pl. Reply in Supp. Summ. J. at 4 n.8; Pl. Opp'n to Mot. to Strike at 4). It does not contend that that outcome—to the extent it is not merely a function of bronze plans attracting healthier enrollees and therefore confounded with the very problem that the risk-adjustment program seeks to remedy—was so apparent as to render the 2014-2017 rulemakings arbitrary and capricious at the time they occurred. Therefore, because the Court has rejected plaintiff's contention that its 2018-benefit-year comment functioned as a petition for rulemaking under 5 U.S.C. § 553(e) which the agency denied, it need not address this objection. (*See also* Hearing Tr. 36:10-14 (admitting that the effect of risk adjustment on bronze plans is "data driven from hindsight")).

IV. Conclusion

In summary, and for the foregoing reasons, the challenged regulations were not arbitrary and capricious, and therefore did not violate the APA, 5 U.S.C. § 706; nor did they contravene the statute providing for risk adjustment, 42 U.S.C. § 18063. Defendants' motion to strike portions of the administrative record is GRANTED in part and DENIED in part, as set forth above. Defendants' motion for summary judgment is GRANTED, and plaintiff's motion for summary judgment is DENIED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor, IV
United States District Judge

Dated: January 30, 2018